

PCB HCC 08-15

ORIGINAL

YEAR

1 A bill to be entitled
 2 An act relating to drugs, devices, and cosmetics; amending
 3 s. 499.002, F.S.; amending s. 499.003, F.S.; amending s.
 4 499.005, F.S.; amending s. 499.0051, F.S.; amending s.
 5 499.0054, F.S.; amending s. 499.006, F.S.; amending s.
 6 499.007, F.S.; amending s. 499.008, F.S.; amending s.
 7 499.009, F.S.; amending s. 499.01, F.S.; amending s.
 8 499.012, F.S.; amending s. 499.01201, F.S.; amending s.
 9 499.0121, F.S.; creating s. 499.012111, F.S.; repealing s.
 10 499.0122, F.S.; repealing s. 499.013, F.S.; amending s.
 11 499.014, F.S.; amending s. 499.015, F.S.; amending s.
 12 499.023, F.S.; amending s. 499.024, F.S.; amending s.
 13 499.025, F.S.; amending s. 499.028, F.S.; amending s.
 14 499.029, F.S.; amending s. 499.03, F.S.; amending s.
 15 499.032, F.S.; amending s. 499.033, F.S.; amending s.
 16 499.035, F.S.; amending s. 499.039, F.S.; amending s.
 17 499.04, F.S.; amending s. 499.041, F.S.; amending s.
 18 499.05, F.S.; amending s. 499.051, F.S.; amending s.
 19 499.052, F.S.; amending s. 499.055, F.S.; amending s.
 20 499.057, F.S.; amending s. 499.06, F.S.; amending s.
 21 499.062, F.S.; amending s. 499.065, F.S.; amending s.
 22 499.066, F.S.; amending s. 499.0661, F.S.; amending s.
 23 499.067, F.S.; providing an effective date.

24
 25 Be It Enacted by the Legislature of the State of Florida:

26
 27 Section 1. Section 499.002, Florida Statutes, is amended,
 28 section 499.004, Florida Statutes, is renumbered as subsection
 29 (2) of that section and amended, section 499.0053, Florida

PCB HCC 08-15

ORIGINAL

YEAR

30 Statutes, is renumbered as subsection (3) of that section and
 31 amended, section 499.07, Florida Statutes, is renumbered as
 32 subsection (4) of that section and amended, section 499.071,
 33 Florida Statutes, is renumbered as subsection (5) of that section
 34 and amended, and section 499.081, Florida Statutes, is renumbered
 35 as subsection (6) of that section and amended, to read:

36 499.002 Purpose, administration, and enforcement of and
 37 exemption from this part ss. 499.001-499.081.--

38 (1) This part is ~~Sections 499.001-499.081~~ are intended to:

39 (a)~~(1)~~ Safeguard the public health and promote the public
 40 welfare by protecting the public from injury by product use and
 41 by merchandising deceit involving drugs, devices, and cosmetics.

42 (b)~~(2)~~ Provide uniform legislation to be administered so
 43 far as practicable in conformity with the provisions of, and
 44 regulations issued under the authority of, the Federal Food,
 45 Drug, and Cosmetic Act and that portion of the Federal Trade
 46 Commission Act which expressly prohibits the false advertisement
 47 of drugs, devices, and cosmetics.

48 (c)~~(3)~~ Promote thereby uniformity of such state and federal
 49 laws, and their administration and enforcement, throughout the
 50 United States.

51 (2) ~~499.004 Administration and enforcement by~~
 52 ~~department.--~~The department of Health shall administer and
 53 enforce this part ss. 499.001-499.081 to prevent fraud,
 54 adulteration, misbranding, or false advertising in the
 55 preparation, manufacture, repackaging, or distribution of drugs,
 56 devices, and cosmetics.

57 (3) ~~499.0053 Power to administer oaths, take depositions,~~
 58 ~~and issue and serve subpoenas.--~~For the purpose of any

PCB HCC 08-15

ORIGINAL

YEAR

59 | investigation or proceeding conducted by the department under
 60 | this part ss. 499.001-499.081, the department may administer
 61 | oaths, take depositions, issue and serve subpoenas, and compel
 62 | the attendance of witnesses and the production of books, papers,
 63 | documents, or other evidence. The department shall exercise this
 64 | power on its own initiative. Challenges to, and enforcement of,
 65 | the subpoenas and orders shall be handled as provided in s.
 66 | 120.569.

67 | (4) ~~499.07 Duty of prosecuting officer.~~ Each state
 68 | attorney, county attorney, or municipal attorney to whom the
 69 | department or its designated agent reports any violation of this
 70 | part ss. 499.001-499.081 shall cause appropriate proceedings to
 71 | be instituted in the proper courts without delay and to be
 72 | prosecuted in the manner required by law.

73 | (5) ~~499.071 Issuance of warnings for minor~~
 74 | ~~violations.~~ This part does ~~Sections 499.001-499.081~~ do not
 75 | require the department to report, for the institution of
 76 | proceedings under this part ss. 499.001-499.081, minor violations
 77 | of this part ss. 499.001-499.081 when it believes that the public
 78 | interest will be adequately served in the circumstances by a
 79 | suitable written notice or warning.

80 | (6) ~~499.081 Carriers in interstate commerce exempted from~~
 81 | ~~ss. 499.001-499.081.~~ Carriers engaged in interstate commerce are
 82 | not subject to this part ss. 499.001-499.081 if they are engaged
 83 | in the usual course of business as carriers.

84 | Section 2. Section 499.003, Florida Statutes, is amended,
 85 | paragraphs (a)-(f) of subsection (1) of section 499.012, Florida
 86 | Statutes, are renumbered as subsections (54), (55), (51), and
 87 | (47), paragraph (c) of subsection (47), and subsection (52) of

PCB HCC 08-15

ORIGINAL

YEAR

88 that section and amended, paragraphs (3)(f)-(j) and (l)-(n) of
 89 Section 499.029, Florida Statutes, are renumbered as subsections
 90 (22), (24), (25), (26), (34), (39), (40), and (42) of that
 91 section and amended, and subsection (1) of section 499.0661,
 92 Florida Statutes, is renumbered as subsection (37) of that
 93 section and amended, to read:

94 499.003 Definitions of terms used in this part ~~ss. 499.001-~~
 95 ~~499.081.~~--As used in this part ~~ss. 499.001-499.081~~, the term:

96 (1) "Advertisement" means any representation disseminated
 97 in any manner or by any means, other than by labeling, for the
 98 purpose of inducing, or which is likely to induce, directly or
 99 indirectly, the purchase of drugs, devices, or cosmetics.

100 (2) "Affiliated group" means an affiliated group as defined
 101 by s. 1504 of the Internal Revenue Code of 1986, as amended,
 102 which is composed of chain drug entities, including at least 50
 103 retail pharmacies, warehouses, or repackagers, which are members
 104 of the same affiliated group. The affiliated group must disclose
 105 the names of all its members to the department.

106 ~~(3)(2)~~ "Affiliated party" means:

107 (a) A director, officer, trustee, partner, or committee
 108 member of a permittee or applicant or a subsidiary or service
 109 corporation of the permittee or applicant;

110 (b) A person who, directly or indirectly, manages,
 111 controls, or oversees the operation of a permittee or applicant,
 112 regardless of whether such person is a partner, shareholder,
 113 manager, member, officer, director, independent contractor, or
 114 employee of the permittee or applicant;

115 (c) A person who has filed or is required to file a
 116 personal information statement pursuant to s. 499.012(9)~~(4)~~ or is

PCB HCC 08-15

ORIGINAL

YEAR

117 required to be identified in an application for a permit or to
 118 renew a permit pursuant to s. 499.012 (8) ~~(3)~~; or

119 (d) The five largest natural shareholders that own at least
 120 5 percent of the permittee or applicant.

121 (4) ~~(3)~~ "Applicant" means a person applying for a permit or
 122 certification under this part ~~ss. 499.001-499.081~~.

123 (5) ~~(4)~~ "Authenticate" means to affirmatively verify upon
 124 receipt of ~~before any distribution of~~ a prescription ~~legend~~ drug
 125 ~~occurs~~ that each transaction listed on the pedigree paper has
 126 occurred. A wholesale distributor is not required to open a
 127 sealed, medical convenience kit to authenticate a pedigree paper
 128 for a prescription drug contained within the kit.

129 (6) ~~(5)~~ "Certificate of free sale" means a document prepared
 130 by the department which certifies a drug, device, or cosmetic,
 131 that is registered with the department, as one that can be
 132 legally sold in the state.

133 (7) "Chain pharmacy warehouse" means a wholesale
 134 distributor permitted pursuant to s. 499.01 that maintains a
 135 physical location for prescription drugs that functions solely as
 136 a central warehouse to perform intracompany transfers of such
 137 drugs to a member of its affiliated group.

138 (8) ~~(6)~~ "Closed pharmacy" means a pharmacy that is licensed
 139 under chapter 465 and purchases prescription drugs for use by a
 140 limited patient population and not for wholesale distribution or
 141 sale to the public. The term does not include retail pharmacies.

142 (9) ~~(7)~~ "Color" includes black, white, and intermediate
 143 grays.

PCB HCC 08-15

ORIGINAL

YEAR

144 (10)-(8) "Color additive" means, with the exception of any
 145 material which has been or hereafter is exempt under the federal
 146 act, a material that:

147 (a) Is a dye pigment, or other substance, made by a process
 148 of synthesis or similar artifice, or extracted, isolated, or
 149 otherwise derived, with or without intermediate or final change
 150 of identity from a vegetable, animal, mineral, or other source;
 151 or

152 (b) When added or applied to a drug or cosmetic or to the
 153 human body, or any part thereof, is capable alone, or through
 154 reaction with other substances, of imparting color thereto.†

155
 156 ~~except that the term does not include any material which has been~~
 157 ~~or hereafter is exempt under the federal act.~~

158 (11)-(9) "Compressed medical gas" means any liquefied or
 159 vaporized gas that is a prescription drug, whether it is alone or
 160 in combination with other gases.

161 (12)-(10) "Contraband prescription ~~legend~~ drug" means any
 162 adulterated drug, as defined in s. 499.006, any counterfeit drug,
 163 as defined in this section, and also means any prescription
 164 ~~legend~~ drug for which a pedigree paper does not exist, or for
 165 which the pedigree paper in existence has been forged,
 166 counterfeited, falsely created, or contains any altered, false,
 167 or misrepresented matter.

168 (13)-(11) "Cosmetic" means an article, with the exception of
 169 soap, that is:

170 (a) Intended to be rubbed, poured, sprinkled, or sprayed
 171 on; introduced into; or otherwise applied to the human body or

PCB HCC 08-15

ORIGINAL

YEAR

172 any part thereof for cleansing, beautifying, promoting
 173 attractiveness, or altering the appearance; or

174 (b) Intended for use as a component of any such article.~~7~~

175

176 ~~except that the term does not include soap.~~

177 (14)~~(12)~~ "Counterfeit drug," "counterfeit device," or
 178 "counterfeit cosmetic" means a drug, device, or cosmetic which,
 179 or the container, seal, or labeling of which, without
 180 authorization, bears the trademark, trade name, or other
 181 identifying mark, imprint, or device, or any likeness thereof, of
 182 a drug, device, or cosmetic manufacturer, processor, packer, or
 183 distributor other than the person that in fact manufactured,
 184 processed, packed, or distributed that drug, device, or cosmetic
 185 and which thereby falsely purports or is represented to be the
 186 product of, or to have been packed or distributed by, that other
 187 drug, device, or cosmetic manufacturer, processor, packer, or
 188 distributor.

189 (15)~~(13)~~ "Department" means the Department of Health.

190 (16)~~(14)~~ "Device" means any instrument, apparatus,
 191 implement, machine, contrivance, implant, in vitro reagent, or
 192 other similar or related article, including its components,
 193 parts, or accessories, which is:

194 (a) Recognized in the current edition of the United States
 195 Pharmacopoeia and National Formulary, or any supplement thereof,

196 (b) Intended for use in the diagnosis, cure, mitigation,
 197 treatment, therapy, or prevention of disease in humans or other
 198 animals, or

199 (c) Intended to affect the structure or any function of the
 200 body of humans or other animals,

PCB HCC 08-15

ORIGINAL

YEAR

201
 202 and ~~that which~~ does not achieve any of its principal intended
 203 purposes through chemical action within or on the body of humans
 204 or other animals and which is not dependent upon being
 205 metabolized for the achievement of any of its principal intended
 206 purposes.

207 (17)~~(15)~~ "Distribute" or "distribution" means to sell;
 208 offer to sell; give away; transfer, whether by passage of title,
 209 physical movement, or both; deliver; or offer to deliver. The
 210 term does not mean to administer or dispense.

211 (18) "Drop shipment" means the sale of a prescription drug
 212 from a manufacturer to a wholesale distributor, where the
 213 wholesale distributor takes title to, but not possession of, the
 214 prescription drug and the manufacturer of the prescription drug
 215 ships the prescription drug directly to a chain pharmacy
 216 warehouse or a person authorized by law to purchase prescription
 217 drugs for the purpose of administering or dispensing the drug, as
 218 defined in s. 465.003.

219 ~~(16) "Diverted from the legal channels of distribution for~~
 220 ~~prescription drugs" means an adulterated drug pursuant to s.~~
 221 ~~499.006(10).~~

222 (19)~~(17)~~ "Drug" means an article that is:

223 (a) Recognized in the current edition of the United States
 224 Pharmacopoeia and National Formulary, official Homeopathic
 225 Pharmacopoeia of the United States, or any supplement to any of
 226 those publications;

227 (b) Intended for use in the diagnosis, cure, mitigation,
 228 treatment, therapy, or prevention of disease in humans or other
 229 animals;

PCB HCC 08-15

ORIGINAL

YEAR

230 (c) Intended to affect the structure or any function of the
231 body of humans or other animals; or

232 (d) Intended for use as a component of any article
233 specified in paragraph (a), paragraph (b), or paragraph (c), but
234 does not include devices or their components, parts, or
235 accessories.

236 (20)~~(18)~~ "Establishment" means a place of business at one
237 general physical location.

238 (21)~~(19)~~ "Federal act" means the Federal Food, Drug, and
239 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

240 (22)~~(20)~~ "Freight forwarder" means a person who receives
241 prescription ~~legend~~ drugs which are owned by another person and
242 designated by that person for export, and exports those
243 prescription ~~legend~~ drugs.

244 (23)~~(9)~~ "Health care clinic" means a health care clinic
245 licensed under part X of chapter 400.

246 (24)~~(21)~~ "Health care entity" means a closed pharmacy or
247 any person, organization, or business entity that provides
248 diagnostic, medical, surgical, or dental treatment or care, or
249 chronic or rehabilitative care, but does not include any
250 wholesale distributor or retail pharmacy licensed under state law
251 to deal in prescription drugs.

252 (25)~~(f)~~ "Health care facility" means a health care facility
253 licensed under chapter 395.

254 (26)~~(h)~~ "Hospice" means a corporation licensed under part
255 IV of chapter 400.

256 (27)~~(i)~~ "Hospital" means a facility as defined in s.
257 395.002 and licensed under chapter 395.

PCB HCC 08-15

ORIGINAL

YEAR

258 | (28)~~(22)~~ "Immediate container" does not include package
259 | liners.

260 | (29)~~(23)~~ "Label" means a display of written, printed, or
261 | graphic matter upon the immediate container of any drug, device,
262 | or cosmetic. A requirement made by or under authority of this
263 | part ~~ss. 499.001-499.081~~ or rules adopted under those sections
264 | that any word, statement, or other information appear on the
265 | label is not complied with unless such word, statement, or other
266 | information also appears on the outside container or wrapper, if
267 | any, of the retail package of such drug, device, or cosmetic or
268 | is easily legible through the outside container or wrapper.

269 | (30)~~(24)~~ "Labeling" means all labels and other written,
270 | printed, or graphic matters:

271 | (a) Upon a drug, device, or cosmetic, or any of its
272 | containers or wrappers; or

273 | (b) Accompanying or related to such drug, device, or
274 | cosmetic.

275 | ~~(25) "Legend drug," "prescription drug," or "medicinal~~
276 | ~~drug" means any drug, including, but not limited to, finished~~
277 | ~~dosage forms, or active ingredients subject to, defined by, or~~
278 | ~~described by s. 503(b) of the Federal Food, Drug, and Cosmetic~~
279 | ~~Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or~~
280 | ~~(c).~~

281 | ~~(26) "Legend drug label" means any display of written,~~
282 | ~~printed, or graphic matter upon the immediate container of any~~
283 | ~~legend drug prior to its dispensing to an individual patient~~
284 | ~~pursuant to a prescription of a practitioner authorized by law to~~
285 | ~~prescribe.~~

PCB HCC 08-15

ORIGINAL

YEAR

286 | ~~(31)-(27)~~ "Manufacture" means the preparation, deriving,
 287 | compounding, propagation, processing, producing, or fabrication
 288 | of any drug, device, or cosmetic.

289 | ~~(32)-(28)~~ "Manufacturer" means a person who prepares,
 290 | derives, manufactures, or produces a drug, device, or cosmetic.
 291 | The term excludes pharmacies that are operating in compliance
 292 | with pharmacy practice standards as defined in chapter 465 and
 293 | rules adopted under that chapter. "Manufacturer" also means the
 294 | holder or holders of a New Drug Application (NDA), an Abbreviated
 295 | New Drug Application (ANDA), a Biologics License Application
 296 | (BLA), or a New Animal Drug Application (NADA), provided that
 297 | such application has become effective or is otherwise approved
 298 | consistent with s. 499.023; a private label distributor for whom
 299 | the private label distributor's prescription drugs are originally
 300 | manufactured and labeled for the distributor and have not been
 301 | repackaged; or the distribution point for the manufacturer,
 302 | contract manufacturer or private label distributor whether the
 303 | establishment is a member of the manufacturer's affiliated group
 304 | or is a contract distribution site.

305 | ~~(33)-(29)~~ "New drug" means:

306 | (a) Any drug the composition of which is such that the drug
 307 | is not generally recognized, among experts qualified by
 308 | scientific training and experience to evaluate the safety and
 309 | effectiveness of drugs, as safe and effective for use under the
 310 | conditions prescribed, recommended, or suggested in the labeling
 311 | of that drug; or

312 | (b) Any drug the composition of which is such that the
 313 | drug, as a result of investigations to determine its safety and
 314 | effectiveness for use under certain conditions, has been

PCB HCC 08-15

ORIGINAL

YEAR

315 | recognized for use under such conditions, but which drug has not,
 316 | other than in those investigations, been used to a material
 317 | extent or for a material time under such conditions.

318 | (34) "Normal distribution chain" means a wholesale
 319 | distribution of a prescription drug where the wholesale
 320 | distributor purchases and receives the specific unit of the
 321 | prescription drug directly from the manufacturer and distributes
 322 | the prescription drug directly, or through one or more
 323 | intracompany transfers, to a chain pharmacy warehouse or a person
 324 | authorized by law to purchase prescription drugs for the purpose
 325 | of administering or dispensing the drug, as defined in s.
 326 | 465.003. For purposes of this subsection, "intracompany" means
 327 | any transaction or transfer between any parent, division, or
 328 | subsidiary wholly owned by a corporate entity.

329 | (35)(j) "Nursing home" means a facility licensed under part
 330 | II of chapter 400.

331 | (36)(30) "Official compendium" means the current edition of
 332 | the official United States Pharmacopoeia and National Formulary,
 333 | or any supplement thereto.

334 | (37)(31) "Pedigree paper" means-

335 | ~~(a) Effective July 1, 2006, a document in written or~~
 336 | ~~electronic form approved by the department that contains of~~
 337 | ~~Health and containing information required by s. 499.012111~~
 338 | ~~regarding the sale and that records each distribution of any~~
 339 | ~~given prescription legend drug, from sale by a pharmaceutical~~
 340 | ~~manufacturer, through acquisition and sale by any wholesaler or~~
 341 | ~~repackager, until final sale to a pharmacy or other person~~
 342 | ~~administering or dispensing the drug. The information required to~~
 343 | ~~be included on the form approved by the department pursuant to~~

PCB HCC 08-15

ORIGINAL

YEAR

344 ~~this paragraph must at least detail the amount of the legend~~
 345 ~~drug; its dosage form and strength; its lot numbers; the name and~~
 346 ~~address of each owner of the legend drug and his or her~~
 347 ~~signature; its shipping information, including the name and~~
 348 ~~address of each person certifying delivery or receipt of the~~
 349 ~~legend drug; an invoice number, a shipping document number, or~~
 350 ~~another number uniquely identifying the transaction; and a~~
 351 ~~certification that the recipient wholesaler has authenticated the~~
 352 ~~pedigree papers. If the manufacturer or repackager has uniquely~~
 353 ~~serialized the individual legend drug unit, that identifier must~~
 354 ~~also be included on the form approved pursuant to this paragraph.~~
 355 ~~It must also include the name, address, telephone number and, if~~
 356 ~~available, e-mail contact information of each wholesaler involved~~
 357 ~~in the chain of the legend drug's custody; or~~

358 ~~(b) A statement, under oath, in written or electronic form,~~
 359 ~~confirming that a wholesale distributor purchases and receives~~
 360 ~~the specific unit of the prescription drug directly from the~~
 361 ~~manufacturer of the prescription drug and distributes the~~
 362 ~~prescription drug directly, or through an intracompany transfer,~~
 363 ~~to a chain pharmacy warehouse or a person authorized by law to~~
 364 ~~purchase prescription drugs for the purpose of administering or~~
 365 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~
 366 ~~this subsection, the term "chain pharmacy warehouse" means a~~
 367 ~~wholesale distributor permitted pursuant to s. 499.01 that~~
 368 ~~maintains a physical location for prescription drugs that~~
 369 ~~functions solely as a central warehouse to perform intracompany~~
 370 ~~transfers of such drugs to a member of its affiliated group as~~
 371 ~~described in s. 499.0121(6)(f)1.~~

PCB HCC 08-15

ORIGINAL

YEAR

372 ~~1. The information required to be included pursuant to this~~
 373 ~~paragraph must include:~~

374 ~~a. The following statement: "This wholesale distributor~~
 375 ~~purchased the specific unit of the prescription drug directly~~
 376 ~~from the manufacturer."~~

377 ~~b. The manufacturer's national drug code identifier and the~~
 378 ~~name and address of the wholesaler and the purchaser of the~~
 379 ~~prescription drug.~~

380 ~~e. The name of the prescription drug as it appears on the~~
 381 ~~label.~~

382 ~~d. The quantity, dosage form, and strength of the~~
 383 ~~prescription drug.~~

384 ~~2. The wholesale distributor must also maintain and make~~
 385 ~~available to the department, upon request, the point of origin of~~
 386 ~~the prescription drugs, including intracompany transfers; the~~
 387 ~~date of the shipment from the manufacturer to the wholesale~~
 388 ~~distributor; the lot numbers of such drugs; and the invoice~~
 389 ~~numbers from the manufacturer.~~

390 ~~(38)(1) DEFINITION. As used in this section, the term~~
 391 ~~"Permittee" means any person holding a permit issued pursuant to~~
 392 ~~s. 499.012.~~

393

394 ~~The department may adopt rules and forms relating to the~~
 395 ~~requirements of this subsection.~~

396 ~~(39)(32)~~ "Person" means any individual, child, joint
 397 venture, syndicate, fiduciary, partnership, corporation, division
 398 of a corporation, firm, trust, business trust, company, estate,
 399 public or private institution, association, organization, group,
 400 city, county, city and county, political subdivision of this

PCB HCC 08-15

ORIGINAL

YEAR

401 state, other governmental agency within this state, and any
 402 representative, agent, or agency of any of the foregoing, or any
 403 other group or combination of the foregoing.

404 (40)~~(1)~~ "Pharmacist" means a person licensed under chapter
 405 465.

406 (41)~~(m)~~ "Pharmacy" means an entity licensed under chapter
 407 465.

408 (42)~~(33)~~ "Prepackaged drug product" means a drug that
 409 originally was in finished packaged form sealed by a manufacturer
 410 and that is placed in a properly labeled container by a pharmacy
 411 or practitioner authorized to dispense pursuant to chapter 465
 412 for the purpose of dispensing in the establishment in which the
 413 prepackaging occurred.

414 (43)~~(n)~~ "Prescribing practitioner" means a physician
 415 licensed under chapters ~~chapter~~ 458 or 459 or any other medical
 416 professional with authority under state law to prescribe cancer
 417 medication.

418 (44) "Prescription drug" means a prescription, medicinal,
 419 or legend drug, including, but not limited to, finished dosage
 420 forms or active ingredients subject to, defined by, or described
 421 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or ss.
 422 465.003(8), 499.007(13), or 499.003(11), (47), or (54).

423 (45) "Prescription drug label" means any display of
 424 written, printed, or graphic matter upon the immediate container
 425 of any prescription drug prior to its dispensing to an individual
 426 patient pursuant to a prescription of a practitioner authorized
 427 by law to prescribe.

428 (46)~~(34)~~ "Prescription label" means any display of written,
 429 printed, or graphic matter upon the immediate container of any

PCB HCC 08-15

ORIGINAL

YEAR

430 prescription ~~legend~~ drug dispensed pursuant to a prescription of
 431 a practitioner authorized by law to prescribe.

432 ~~(47)-(35)~~ "Prescription medical oxygen" means oxygen USP
 433 which is a drug that can only be sold on the order or
 434 prescription of a practitioner authorized by law to prescribe.
 435 The label of prescription medical oxygen must comply with current
 436 labeling requirements for oxygen under the Federal Food, Drug,
 437 and Cosmetic Act.

438 ~~(48)-(d)~~ "Primary wholesale distributor ~~wholesaler~~" means
 439 any wholesale distributor that:

440 ~~(a)1.~~ Purchased 90 percent or more of the total dollar
 441 volume of its purchases of prescription drugs directly from
 442 manufacturers in the previous year; and

443 ~~(b)1.2.a.~~ Directly purchased prescription drugs from not
 444 fewer than 50 different prescription drug manufacturers in the
 445 previous year; or

446 ~~2.b.~~ Has, or the affiliated group, as defined in s. 1504 of
 447 the Internal Revenue Code, of which the wholesale distributor is
 448 a member has, not fewer than 250 employees.

449 ~~(c)~~ For purposes of this subsection, ~~(e)~~ "directly from
 450 manufacturers ~~a manufacturer~~" means:

451 1. Purchases made by the wholesale distributor directly
 452 from the manufacturer of prescription drugs; and

453 2. Transfers from a member of an affiliated group, as
 454 defined in s. 1504 of the Internal Revenue Code, of which the
 455 wholesale distributor is a member, if:

456 a. The affiliated group purchases 90 percent or more of the
 457 total dollar volume of its purchases of prescription drugs from
 458 the manufacturer in the previous year; and

PCB HCC 08-15

ORIGINAL

YEAR

459 | b. The wholesale distributor discloses to the department
 460 | the names of all members of the affiliated group of which the
 461 | wholesale distributor is a member and the affiliated group agrees
 462 | in writing to provide records on prescription drug purchases by
 463 | the members of the affiliated group not later than 48 hours after
 464 | the department requests access to such records, regardless of the
 465 | location where the records are stored.

466 | (49)~~(36)~~ "Proprietary drug," or "OTC drug," means a patent
 467 | or over-the-counter drug in its unbroken, original package, which
 468 | drug is sold to the public by, or under the authority of, the
 469 | manufacturer or primary distributor thereof, is not misbranded
 470 | under the provisions of this part ~~ss. 499.001-499.081~~, and can be
 471 | purchased without a prescription.

472 | (50)~~(37)~~ "Repackage" includes repacking or otherwise
 473 | changing the container, wrapper, or labeling to further the
 474 | distribution of the drug, device, or cosmetic.

475 | (51)~~(38)~~ "Repackager" means a person who repackages. The
 476 | term excludes pharmacies that are operating in compliance with
 477 | pharmacy practice standards as defined in chapter 465 and rules
 478 | adopted under that chapter.

479 | (52)~~(e)~~ "Retail pharmacy" means a community pharmacy
 480 | licensed under chapter 465 that purchases prescription drugs at
 481 | fair market prices and provides prescription services to the
 482 | public.

483 | (53)~~(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means
 484 | a wholesale distributor that is not a primary wholesaler.

485 | (54)~~(39)~~ "Veterinary prescription drug" means a
 486 | prescription ~~legend~~ drug intended solely for veterinary use. The
 487 | label of the drug must bear the statement, "Caution: Federal law

PCB HCC 08-15

ORIGINAL

YEAR

488 restricts this drug to sale by or on the order of a licensed
 489 veterinarian."

490 ~~(40) "Veterinary prescription drug wholesaler" means any~~
 491 ~~person engaged in wholesale distribution of veterinary~~
 492 ~~prescription drugs in or into this state.~~

493 (55) ~~(a)~~ "Wholesale distribution" means distribution of
 494 prescription drugs to persons other than a consumer or patient,
 495 but does not include:

496 (a) ~~1.~~ Any of the following activities, which is not a
 497 violation of s. 499.005(21) if such activity is conducted in
 498 accordance with s. 499.014:

499 1.a. ~~1.~~ The purchase or other acquisition by a hospital or
 500 other health care entity that is a member of a group purchasing
 501 organization of a prescription drug for its own use from the
 502 group purchasing organization or from other hospitals or health
 503 care entities that are members of that organization.

504 2.b. ~~2.~~ The sale, purchase, or trade of a prescription drug or
 505 an offer to sell, purchase, or trade a prescription drug by a
 506 charitable organization described in s. 501(c)(3) of the Internal
 507 Revenue Code of 1986, as amended and revised, to a nonprofit
 508 affiliate of the organization to the extent otherwise permitted
 509 by law.

510 3.e. ~~3.~~ The sale, purchase, or trade of a prescription drug or
 511 an offer to sell, purchase, or trade a prescription drug among
 512 hospitals or other health care entities that are under common
 513 control. For purposes of this section, "common control" means the
 514 power to direct or cause the direction of the management and
 515 policies of a person or an organization, whether by ownership of
 516 stock, by voting rights, by contract, or otherwise.

PCB HCC 08-15

ORIGINAL

YEAR

517 ~~4.d.~~ The sale, purchase, trade, or other transfer of a
 518 prescription drug from or for any federal, state, or local
 519 government agency or any entity eligible to purchase prescription
 520 drugs at public health services prices pursuant to Pub. L. No.
 521 102-585, s. 602 to a contract provider or its subcontractor for
 522 eligible patients of the agency or entity under the following
 523 conditions:

524 ~~a.(I)~~ The agency or entity must obtain written
 525 authorization for the sale, purchase, trade, or other transfer of
 526 a prescription drug under this sub-subparagraph from the State
 527 Surgeon General or his or her designee.

528 ~~b.(II)~~ The contract provider or subcontractor must be
 529 authorized by law to administer or dispense prescription drugs.

530 ~~c.(III)~~ In the case of a subcontractor, the agency or
 531 entity must be a party to and execute the subcontract.

532 ~~d.(IV)~~ A contract provider or subcontractor must maintain
 533 separate and apart from other prescription drug inventory any
 534 prescription drugs of the agency or entity in its possession.

535 ~~e.(V)~~ The contract provider and subcontractor must maintain
 536 and produce immediately for inspection all records of movement or
 537 transfer of all the prescription drugs belonging to the agency or
 538 entity, including, but not limited to, the records of receipt and
 539 disposition of prescription drugs. Each contractor and
 540 subcontractor dispensing or administering these drugs must
 541 maintain and produce records documenting the dispensing or
 542 administration. Records that are required to be maintained
 543 include, but are not limited to, a perpetual inventory itemizing
 544 drugs received and drugs dispensed by prescription number or

PCB HCC 08-15

ORIGINAL

YEAR

545 administered by patient identifier, which must be submitted to
 546 the agency or entity quarterly.

547 f.~~(VI)~~ The contract provider or subcontractor may
 548 administer or dispense the prescription drugs only to the
 549 eligible patients of the agency or entity or must return the
 550 prescription drugs for or to the agency or entity. The contract
 551 provider or subcontractor must require proof from each person
 552 seeking to fill a prescription or obtain treatment that the
 553 person is an eligible patient of the agency or entity and must,
 554 at a minimum, maintain a copy of this proof as part of the
 555 records of the contractor or subcontractor required under ~~sub-~~
 556 sub-subparagraph e.~~(V)~~.

557 g.~~(VII)~~ In addition to the departmental inspection
 558 authority set forth in s. 499.051, the establishment of the
 559 contract provider and subcontractor and all records pertaining to
 560 prescription drugs subject to this sub-subparagraph shall be
 561 subject to inspection by the agency or entity. All records
 562 relating to prescription drugs of a manufacturer under this sub-
 563 subparagraph shall be subject to audit by the manufacturer of
 564 those drugs, without identifying individual patient information.

565 (b)2. Any of the following activities, which is not a
 566 violation of s. 499.005(21) if such activity is conducted in
 567 accordance with rules established by the department:

568 1.a. The sale, purchase, or trade of a prescription drug
 569 among federal, state, or local government health care entities
 570 that are under common control and are authorized to purchase such
 571 prescription drug.

572 2.b. The sale, purchase, or trade of a prescription drug or
 573 an offer to sell, purchase, or trade a prescription drug for

PCB HCC 08-15

ORIGINAL

YEAR

574 emergency medical reasons. For purposes of this ~~sub~~-subparagraph,
 575 the term "emergency medical reasons" includes transfers of
 576 prescription drugs by a retail pharmacy to another retail
 577 pharmacy to alleviate a temporary shortage.

578 3.e. The transfer of a prescription drug acquired by a
 579 medical director on behalf of a licensed emergency medical
 580 services provider to that emergency medical services provider and
 581 its transport vehicles for use in accordance with the provider's
 582 license under chapter 401.

583 4.d. The revocation of a sale or the return of a
 584 prescription drug to the person's prescription drug wholesale
 585 supplier.

586 5.e. The donation of a prescription drug by a health care
 587 entity to a charitable organization that has been granted an
 588 exemption under s. 501(c)(3) of the Internal Revenue Code of
 589 1986, as amended, and that is authorized to possess prescription
 590 drugs.

591 6.f. The transfer of a prescription drug by a person
 592 authorized to purchase or receive prescription drugs to a person
 593 licensed or permitted to handle reverse distributions or
 594 destruction under the laws of the jurisdiction in which the
 595 person handling the reverse distribution or destruction receives
 596 the drug.

597 7.g. The transfer of a prescription drug by a hospital or
 598 other health care entity to a person licensed under this chapter
 599 to repackaging prescription drugs for the purpose of repackaging
 600 the prescription drug for use by that hospital, or other health
 601 care entity and other health care entities that are under common
 602 control, if ownership of the prescription drugs remains with the

PCB HCC 08-15

ORIGINAL

YEAR

603 hospital or other health care entity at all times. In addition to
 604 the recordkeeping requirements of s. 499.0121(6), the hospital or
 605 health care entity that transfers prescription drugs pursuant to
 606 this ~~sub~~-subparagraph must reconcile all drugs transferred and
 607 returned and resolve any discrepancies in a timely manner.

608 (c)~~3~~. The distribution of prescription drug samples by
 609 manufacturers' representatives or distributors' representatives
 610 conducted in accordance with s. 499.028.

611 (d)~~4~~. The sale, purchase, or trade of blood and blood
 612 components intended for transfusion. As used in this
 613 subparagraph, the term "blood" means whole blood collected from a
 614 single donor and processed either for transfusion or further
 615 manufacturing, and the term "blood components" means that part of
 616 the blood separated by physical or mechanical means.

617 (e)~~5~~. The lawful dispensing of a prescription drug in
 618 accordance with chapter 465.

619 (f)~~6~~. The sale, purchase, or trade of a prescription drug
 620 between pharmacies as a result of a sale, transfer, merger, or
 621 consolidation of all or part of the business of the pharmacies
 622 from or with another pharmacy, whether accomplished as a purchase
 623 and sale of stock or of business assets.

624 (56)~~(b)~~ "Wholesale distributor" means any person engaged in
 625 wholesale distribution of prescription drugs in or into this
 626 state, including, but not limited to, manufacturers; repackagers;
 627 own-label distributors; jobbers; private-label distributors;
 628 brokers; warehouses, including manufacturers' and distributors'
 629 warehouses, chain drug warehouses, and wholesale drug warehouses;
 630 independent wholesale drug traders; exporters; retail pharmacies;
 631 and the agents thereof that conduct wholesale distributions.

PCB HCC 08-15

ORIGINAL

YEAR

632 Section 3. Section 499.005, Florida Statutes, is amended to
 633 read:

634 499.005 Prohibited acts.--It is unlawful for a person to
 635 perform or cause the performance of any of the following acts in
 636 this state:

637 (1) The manufacture, repackaging, sale, delivery, or
 638 holding or offering for sale of any drug, device, or cosmetic
 639 that is adulterated or misbranded or has otherwise been rendered
 640 unfit for human or animal use.

641 (2) The adulteration or misbranding of any drug, device, or
 642 cosmetic.

643 (3) The receipt of any drug, device, or cosmetic that is
 644 adulterated or misbranded, and the delivery or proffered delivery
 645 of such drug, device, or cosmetic, for pay or otherwise.

646 (4) The sale, distribution, purchase, trade, holding, or
 647 offering of any drug, device, or cosmetic in violation of this
 648 part ~~ss. 499.001-499.081~~.

649 (5) The dissemination of any false or misleading
 650 advertisement of a drug, device, or cosmetic.

651 (6) The refusal or constructive refusal:

652 (a) To allow the department to enter or inspect an
 653 establishment in which drugs, devices, or cosmetics are
 654 manufactured, processed, repackaged, sold, brokered, or held;

655 (b) To allow inspection of any record of that
 656 establishment;

657 (c) To allow the department to enter and inspect any
 658 vehicle that is being used to transport drugs, devices, or
 659 cosmetics; or

PCB HCC 08-15

ORIGINAL

YEAR

660 (d) To allow the department to take samples of any drug,
661 device, or cosmetic.

662 (7) The purchase or sale of prescription drugs for
663 wholesale distribution in exchange for currency, as defined in s.
664 560.103(6).

665 (8) Committing any act that causes a drug, device, or
666 cosmetic to be a counterfeit drug, device, or cosmetic; or
667 selling, dispensing, or holding for sale a counterfeit drug,
668 device, or cosmetic.

669 (9) The alteration, mutilation, destruction, obliteration,
670 or removal of the whole or any part of the labeling of a drug,
671 device, or cosmetic, or the doing of any other act with respect
672 to a drug, device, or cosmetic, if the act is done while the
673 drug, device, or cosmetic is held for sale and the act results in
674 the drug, device, or cosmetic being misbranded.

675 (10) Forging; counterfeiting; simulating; falsely
676 representing any drug, device, or cosmetic; or, without the
677 authority of the manufacturer, using any mark, stamp, tag, label,
678 or other identification device authorized or required by rules
679 adopted under this part ~~ss. 499.001-499.081~~.

680 (11) The use, on the labeling of any drug or in any
681 advertisement relating to such drug, of any representation or
682 suggestion that an application of the drug is effective when it
683 is not or that the drug complies with this part ~~ss. 499.001-~~
684 ~~499.081~~ when it does not.

685 (12) The possession of any drug in violation of this part
686 ~~ss. 499.001-499.081~~.

687 (13) The sale, delivery, holding, or offering for sale of
688 any self-testing kits designed to tell persons their status

PCB HCC 08-15

ORIGINAL

YEAR

689 concerning human immunodeficiency virus or acquired immune
 690 deficiency syndrome or related disorders or conditions. This
 691 prohibition shall not apply to home access HIV test kits approved
 692 for distribution and sale by the United States Food and Drug
 693 Administration.

694 (14) The purchase or receipt of a prescription ~~legend~~ drug
 695 from a person that is not authorized under this chapter to
 696 distribute prescription ~~legend~~ drugs to that purchaser or
 697 recipient.

698 (15) The sale or transfer of a prescription ~~legend~~ drug to
 699 a person that is not authorized under the law of the jurisdiction
 700 in which the person receives the drug to purchase or possess
 701 prescription ~~legend~~ drugs from the person selling or transferring
 702 the prescription ~~legend~~ drug.

703 (16) The purchase or receipt of a compressed medical gas
 704 from a person that is not authorized under this chapter to
 705 distribute compressed medical gases.

706 (17) The sale, purchase, or trade, or the offer to sell,
 707 purchase, or trade, a drug sample as defined in s. 499.028; the
 708 distribution of a drug sample in violation of s. 499.028; or the
 709 failure to otherwise comply with s. 499.028.

710 (18) Failure to maintain records as required by this part
 711 ~~ss. 499.001-499.081~~ and rules adopted under those sections.

712 (19) Providing the department with false or fraudulent
 713 records, or making false or fraudulent statements, regarding any
 714 matter within the provisions of this chapter.

715 (20) The importation of a prescription ~~legend~~ drug except
 716 as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic
 717 Act.

PCB HCC 08-15

ORIGINAL

YEAR

- 718 (21) The wholesale distribution of any prescription drug
 719 that was:
- 720 (a) Purchased by a public or private hospital or other
 721 health care entity; or
- 722 (b) Donated or supplied at a reduced price to a charitable
 723 organization.
- 724 (22) Failure to obtain a permit or registration, or
 725 operating without a valid permit when a permit or registration is
 726 required by this part ~~ss. 499.001-499.081~~ for that activity.
- 727 (23) Obtaining or attempting to obtain a prescription drug
 728 or device by fraud, deceit, misrepresentation or subterfuge, or
 729 engaging in misrepresentation or fraud in the distribution of a
 730 drug or device.
- 731 (24) The distribution of a prescription ~~legend~~ device to
 732 the patient or ultimate consumer without a prescription or order
 733 from a practitioner licensed by law to use or prescribe the
 734 device.
- 735 (25) Charging a dispensing fee for dispensing,
 736 administering, or distributing a prescription drug sample.
- 737 (26) Removing a pharmacy's dispensing label from a
 738 dispensed prescription drug with the intent to further distribute
 739 the prescription drug.
- 740 (27) Distributing a prescription drug that was previously
 741 dispensed by a licensed pharmacy, unless such distribution was
 742 authorized in chapter 465 or the rules adopted under chapter 465.
- 743 (28) Failure to acquire ~~obtain~~ or deliver ~~pass on~~ a
 744 pedigree paper where required under this part.
- 745 (29) The receipt of a prescription drug pursuant to a
 746 wholesale distribution without previously or simultaneously

PCB HCC 08-15

ORIGINAL

YEAR

747 ~~either first~~ receiving a pedigree paper that was attested to as
 748 accurate and complete by the wholesale distributor, where
 749 required under this part ~~or complying with the provisions of s.~~
 750 ~~499.0121(6)(d)5.~~

751 Section 4. Section 499.0051, Florida Statutes, is amended,
 752 section 499.0052, Florida Statutes, is renumbered as subsection
 753 (7) of that section and amended, section 499.00535, Florida
 754 Statutes, is renumbered as subsection (9) of that section and
 755 amended, section 499.00545, Florida Statutes, is renumbered as
 756 subsection (10) of that section and amended, section 499.069,
 757 Florida Statutes, is renumbered as subsection (11) of that
 758 section and amended, and section 499.0691, Florida Statutes, is
 759 renumbered as subsections (12)-(15) of that section and amended,
 760 to read:

761 499.0051 Criminal acts ~~involving contraband or adulterated~~
 762 ~~drugs.~~--

763 (1) FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.--

764 (a) A person, other than a manufacturer, engaged in the
 765 wholesale distribution of prescription legend ~~legend~~ drugs who fails to
 766 deliver to another person complete and accurate pedigree papers
 767 concerning a prescription legend ~~legend~~ drug or contraband prescription
 768 ~~legend~~ drug prior to, or simultaneous with, the transfer of,
 769 ~~transferring~~ the prescription legend ~~legend~~ drug or contraband
 770 prescription legend ~~legend~~ drug to another person commits a felony of
 771 the third degree, punishable as provided in s. 775.082, s.
 772 775.083, or s. 775.084.

773 (b) A person engaged in the wholesale distribution of
 774 prescription legend ~~legend~~ drugs who fails to acquire complete and
 775 accurate pedigree papers concerning a prescription legend ~~legend~~ drug or

PCB HCC 08-15

ORIGINAL

YEAR

776 | contraband prescription legend drug prior to, or simultaneous
 777 | with, the receipt of obtaining the prescription legend drug or
 778 | contraband prescription legend drug from another person commits a
 779 | felony of the third degree, punishable as provided in s. 775.082,
 780 | s. 775.083, or s. 775.084.

781 | (c) Any person who knowingly destroys, alters, conceals, or
 782 | fails to maintain complete and accurate pedigree papers
 783 | concerning any prescription legend drug or contraband
 784 | prescription legend drug in his or her possession commits a
 785 | felony of the third degree, punishable as provided in s. 775.082,
 786 | s. 775.083, or s. 775.084.

787 | (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.--Effective
 788 | July 1, 2006:

789 | (a) A person engaged in the wholesale distribution of
 790 | prescription legend drugs who is in possession of pedigree papers
 791 | concerning prescription legend drugs or contraband prescription
 792 | legend drugs and who fails to authenticate the matters contained
 793 | in the pedigree papers and who nevertheless attempts to further
 794 | distribute prescription legend drugs or contraband prescription
 795 | legend drugs commits a felony of the third degree, punishable as
 796 | provided in s. 775.082, s. 775.083, or s. 775.084.

797 | (b) A person in possession of pedigree papers concerning
 798 | prescription legend drugs or contraband prescription legend drugs
 799 | who falsely swears or certifies that he or she has authenticated
 800 | the matters contained in the pedigree papers commits a felony of
 801 | the third degree, punishable as provided in s. 775.082, s.
 802 | 775.083, or s. 775.084.

803 | (3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who
 804 | knowingly forges, counterfeits, or falsely creates any pedigree

PCB HCC 08-15

ORIGINAL

YEAR

805 paper; who falsely represents any factual matter contained on any
 806 pedigree paper; or who knowingly omits to record material
 807 information required to be recorded in a pedigree paper, commits
 808 a felony of the second degree, punishable as provided in s.
 809 775.082, s. 775.083, or s. 775.084.

810 (4) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION ~~LEGEND~~ DRUG
 811 FROM UNAUTHORIZED PERSON.--A person who knowingly purchases or
 812 receives from a person not authorized to distribute prescription
 813 ~~legend~~ drugs under this chapter a prescription ~~legend~~-drug in a
 814 wholesale distribution transaction commits a felony of the second
 815 degree, punishable as provided in s. 775.082, s. 775.083, or s.
 816 775.084.

817 (5) KNOWING SALE OR TRANSFER OF PRESCRIPTION ~~LEGEND~~ DRUG TO
 818 UNAUTHORIZED PERSON.--A person who knowingly sells or transfers
 819 to a person not authorized to purchase or possess prescription
 820 ~~legend~~ drugs, under the law of the jurisdiction in which the
 821 person receives the drug, a prescription ~~legend~~ drug in a
 822 wholesale distribution transaction commits a felony of the second
 823 degree, punishable as provided in s. 775.082, s. 775.083, or s.
 824 775.084.

825 (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO
 826 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is
 827 knowingly in actual or constructive possession of any amount of
 828 contraband prescription ~~legend~~ drugs, who knowingly sells or
 829 delivers, or who possesses with intent to sell or deliver any
 830 amount of contraband prescription ~~legend~~ drugs, commits a felony
 831 of the second degree, punishable as provided in s. 775.082, s.
 832 775.083, or s. 775.084.

PCB HCC 08-15

ORIGINAL

YEAR

833 | (7) KNOWING ~~499.0052~~ TRAFFICKING IN CONTRABAND
 834 | PRESCRIPTION ~~legend~~ DRUGS.--A person who knowingly sells,
 835 | purchases, manufactures, delivers, or brings into this state, or
 836 | who is knowingly in actual or constructive possession of any
 837 | amount of contraband prescription ~~legend~~ drugs valued at \$25,000
 838 | or more commits a felony of the first degree, punishable as
 839 | provided in s. 775.082, s. 775.083, or s. 775.084.

840 | (a) Upon conviction, each defendant shall be ordered to pay
 841 | a mandatory fine according to the following schedule:

842 | 1.~~(1)~~ If the value of contraband prescription ~~legend~~ drugs
 843 | involved is \$25,000 or more, but less than \$100,000, the
 844 | defendant shall pay a mandatory fine of \$25,000. If the defendant
 845 | is a corporation or other person that is not a natural person, it
 846 | shall pay a mandatory fine of \$75,000.

847 | 2.~~(2)~~ If the value of contraband prescription ~~legend~~ drugs
 848 | involved is \$100,000 or more, but less than \$250,000, the
 849 | defendant shall pay a mandatory fine of \$100,000. If the
 850 | defendant is a corporation or other person that is not a natural
 851 | person, it shall pay a mandatory fine of \$300,000.

852 | 3.~~(3)~~ If the value of contraband prescription ~~legend~~ drugs
 853 | involved is \$250,000 or more, the defendant shall pay a mandatory
 854 | fine of \$200,000. If the defendant is a corporation or other
 855 | person that is not a natural person, it shall pay a mandatory
 856 | fine of \$600,000.

857 | (b) As used in this subsection, the term "value" means the
 858 | market value of the property at the time and place of the offense
 859 | or, if such cannot be satisfactorily ascertained, the cost of
 860 | replacement of the property within a reasonable time after the
 861 | offense. Amounts of value of separate contraband prescription

PCB HCC 08-15

ORIGINAL

YEAR

862 ~~legend~~ drugs involved in distinct transactions for the
 863 distribution of the contraband prescription ~~legend~~ drugs
 864 committed pursuant to one scheme or course of conduct, whether
 865 involving the same person or several persons, may be aggregated
 866 in determining the punishment of the offense.

867 (8) ~~(7)~~ KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION
 868 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges, counterfeits,
 869 or falsely creates any prescription label or prescription ~~legend~~
 870 drug label, or who falsely represents any factual matter
 871 contained on any prescription label or prescription ~~legend~~ drug
 872 label, commits a felony of the first degree, punishable as
 873 provided in s. 775.082, s. 775.083, or s. 775.084.

874 (9) KNOWING ~~499.00535~~ SALE OR PURCHASE OF CONTRABAND
 875 PRESCRIPTION ~~LEGEND~~ DRUGS RESULTING IN GREAT BODILY HARM.-- A
 876 person who knowingly sells, purchases, manufactures, delivers, or
 877 brings into this state, or who is knowingly in actual or
 878 constructive possession of any amount of contraband prescription
 879 ~~legend~~ drugs, and whose acts in violation of this section result
 880 in great bodily harm to a person, commits a felony of the first
 881 degree, as provided in s. 775.082, s. 775.083, or s. 775.084.

882 (10) KNOWING ~~499.00545~~ SALE OR PURCHASE OF CONTRABAND
 883 PRESCRIPTION ~~LEGEND~~ DRUGS RESULTING IN DEATH.-- A person who
 884 knowingly manufactures, sells, purchases, delivers, or brings
 885 into this state, or who is knowingly in actual or constructive
 886 possession of any amount of contraband prescription ~~legend~~ drugs,
 887 and whose acts in violation of this section result in the death
 888 of a person, commits a felony of the first degree, punishable by
 889 a term of years not exceeding life, as provided in s. 775.082, s.
 890 775.083, or s. 775.084.

PCB HCC 08-15

ORIGINAL

YEAR

891 (11) ~~499.069~~ ~~Criminal punishment~~ FOR VIOLATIONS OF S.
 892 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE
 893 ADVERTISEMENT.--Any person who violates any of the provisions of
 894 s. 499.005 with respect to a device or cosmetic commits a
 895 misdemeanor of the second degree, punishable as provided in s.
 896 775.082 or s. 775.083; but, if the violation is committed after a
 897 conviction of such person under this section has become final,
 898 such person is guilty of a misdemeanor of the first degree,
 899 punishable as provided in s. 775.082 or s. 775.083 or as
 900 otherwise provided in this part, except that any person who
 901 violates subsection (8) or subsection (10) of s. 499.005 with
 902 respect to a device or cosmetic commits a felony of the third
 903 degree, punishable as provided in s. 775.082, s. 775.083, or s.
 904 775.084, or as otherwise provided in this part ~~ss. 499.001-~~
 905 ~~499.081~~.

906 ~~(2)~~—A publisher, radio broadcast licensee, or agency or
 907 medium for the dissemination of an advertisement, except the
 908 manufacturer, wholesaler, or seller of the article to which a
 909 false advertisement relates, is not liable under this subsection
 910 by reason of the dissemination by him or her of such false
 911 advertisement, unless he or she has refused, on the request of
 912 the department, to furnish to the department the name and post
 913 office address of the manufacturer, wholesaler, seller, or
 914 advertising agency that asked him or her to disseminate such
 915 advertisement.

916 (12) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT;
 917 FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS ~~499.0691~~ ~~Criminal~~
 918 ~~punishment for violations related to drugs; dissemination of~~
 919 ~~false advertisement.--~~

PCB HCC 08-15

ORIGINAL

YEAR

920 ~~(1)~~—Any person who violates any of the following provisions
 921 commits a misdemeanor of the second degree, punishable as
 922 provided in s. 775.082 or s. 775.083; but, if the violation is
 923 committed after a conviction of such person under this section
 924 has become final, such person commits a misdemeanor of the first
 925 degree, punishable as provided in s. 775.082 or s. 775.083, or as
 926 otherwise provided in this part ~~ss. 499.001-499.081~~:

927 (a) The manufacture, repackaging, sale, delivery, or
 928 holding or offering for sale of any drug that is adulterated or
 929 misbranded or has otherwise been rendered unfit for human or
 930 animal use.

931 (b) The adulteration or misbranding of any drug intended
 932 for further distribution.

933 (c) The receipt of any drug that is adulterated or
 934 misbranded, and the delivery or proffered delivery of such drug,
 935 for pay or otherwise.

936 (d) The dissemination of any false or misleading
 937 advertisement of a drug.

938 (e) The use, on the labeling of any drug or in any
 939 advertisement relating to such drug, of any representation or
 940 suggestion that an application of the drug is effective when it
 941 is not or that the drug complies with this part ~~ss. 499.001-~~
 942 ~~499.081~~ when it does not.

943 (f) The purchase or receipt of a compressed medical gas
 944 from a person that is not authorized under this chapter to
 945 distribute compressed medical gases.

946 (g) Charging a dispensing fee for dispensing,
 947 administering, or distributing a prescription drug sample.

PCB HCC 08-15

ORIGINAL

YEAR

948 (h) The failure to maintain records related to a drug as
 949 required by this part ~~ss. 499.001-499.081~~ and rules adopted under
 950 those sections, except for pedigree papers, invoices, or shipping
 951 documents related to prescription ~~legend~~ drugs.

952 (i) The possession of any drug in violation of this part
 953 ~~ss. 499.001-499.081~~, except if the violation relates to a
 954 deficiency in pedigree papers.

955 (13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR
 956 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
 957 PRESCRIPTION DRUGS.--(2) Any person who violates any of the

958 following provisions commits a felony of the third degree,
 959 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
 960 or as otherwise provided in this part: ~~ss. 499.001-499.081~~.

961 (a) The refusal or constructive refusal to allow:

962 1. The department to enter or inspect an establishment in
 963 which drugs are manufactured, processed, repackaged, sold,
 964 brokered, or held;

965 2. Inspection of any record of that establishment;

966 3. The department to enter and inspect any vehicle that is
 967 being used to transport drugs; or

968 4. The department to take samples of any drug.

969 (b) The sale, purchase, or trade, or the offer to sell,
 970 purchase, or trade, a drug sample as defined in s. 499.028; the
 971 distribution of a drug sample in violation of s. 499.028; or the
 972 failure to otherwise comply with s. 499.028.

973 (c) Providing the department with false or fraudulent
 974 records, or making false or fraudulent statements, regarding any
 975 matter within the provisions of this chapter related to a drug.

PCB HCC 08-15

ORIGINAL

YEAR

976 (d) The failure to receive, maintain, or provide invoices
 977 and shipping documents, other than pedigree papers, if
 978 applicable, related to the distribution of a prescription legend
 979 drug.

980 (e) The importation of a prescription legend drug for
 981 wholesale distribution, except as provided by s. 801(d) of the
 982 Federal Food, Drug, and Cosmetic Act.

983 (f) The wholesale distribution of ~~any~~ prescription drug
 984 that was:

985 1. Purchased by a public or private hospital or other
 986 health care entity; or

987 2. Donated or supplied at a reduced price to a charitable
 988 organization.

989 (g) The failure to obtain a permit as a prescription drug
 990 wholesale distributor ~~wholesaler~~ when a permit is required by
 991 this part for that activity.

992 (h) Knowingly possessing any adulterated or misbranded
 993 prescription legend drug outside of a designated quarantine area.

994 (i) The purchase or sale of a prescription drugs for
 995 wholesale distribution in exchange for currency, as defined in s.
 996 560.103(6).

997 (14) OTHER VIOLATIONS. ~~-(3)-~~ Any person who violates any of
 998 the following provisions commits a felony of the second degree,
 999 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
 1000 or as otherwise provided in this part: ~~ss. 499.001-499.081.~~

1001 (a) Knowingly manufacturing, repackaging, selling,
 1002 delivering, or holding or offering for sale any drug that is
 1003 adulterated or misbranded or has otherwise been rendered unfit
 1004 for human or animal use.

PCB HCC 08-15

ORIGINAL

YEAR

1005 (b) Knowingly adulterating a drug that is intended for
 1006 further distribution.

1007 (c) Knowingly receiving a drug that is adulterated and
 1008 delivering or proffering delivery of such drug for pay or
 1009 otherwise.

1010 (d) Committing any act that causes a drug to be a
 1011 counterfeit drug, or selling, dispensing, or knowingly holding
 1012 for sale a counterfeit drug.

1013 (e) Forging, counterfeiting, simulating, or falsely
 1014 representing any drug, or, without the authority of the
 1015 manufacturer, using any mark, stamp, tag, label, or other
 1016 identification device authorized or required by rules adopted
 1017 under this part ~~ss. 499.001-499.081~~.

1018 (f) Knowingly obtaining or attempting to obtain a
 1019 prescription drug for wholesale distribution by fraud, deceit,
 1020 misrepresentation, or subterfuge, or engaging in
 1021 misrepresentation or fraud in the distribution of a drug.

1022 (g) Removing a pharmacy's dispensing label from a dispensed
 1023 prescription drug with the intent to further distribute the
 1024 prescription drug.

1025 (h) Knowingly distributing a prescription drug that was
 1026 previously dispensed by a licensed pharmacy, unless such
 1027 distribution was authorized in chapter 465 or the rules adopted
 1028 under chapter 465.

1029 (15) FALSE ADVERTISEMENT. ~~---(4)---~~ A publisher, radio
 1030 broadcast licensee, or agency or medium for the dissemination of
 1031 an advertisement, except the manufacturer, repackager, wholesale
 1032 distributor, or seller of the article to which a false
 1033 advertisement relates, is not liable under subsections (12),

PCB HCC 08-15

ORIGINAL

YEAR

1034 | (13), or (14) ~~this section~~ by reason of the dissemination by him
 1035 | or her of such false advertisement, unless he or she has refused,
 1036 | on the request of the department, to furnish to the department
 1037 | the name and post office address of the manufacturer, repackager,
 1038 | wholesale distributor, seller, or advertising agency that asked
 1039 | him or her to disseminate such advertisement.

1040 | Section 5. Section 499.0054, Florida Statutes, is amended,
 1041 | section 499.0055, Florida Statutes, is renumbered as subsection
 1042 | (2) of that section and amended, and section 499.0057, Florida
 1043 | Statutes, is renumbered as subsection (3) of that section and
 1044 | amended, to read:

1045 | 499.0054 Advertising and labeling of drugs, devices, and
 1046 | cosmetics; exemptions.---

1047 | (1) It is a violation of the Florida Drug and Cosmetic Act
 1048 | to perform or cause the performance of any of the following acts:

1049 | (a) ~~(1)~~ The dissemination of any false advertisement of any
 1050 | drug, device, or cosmetic. An advertisement is false if it is
 1051 | false or misleading in any way.

1052 | (b) ~~(2)~~ The distribution in commerce of any drug, device, or
 1053 | cosmetic, if its labeling or advertising is in violation of this
 1054 | part ~~ss. 499.001-499.081.~~

1055 | (c) ~~(3)~~ The manufacturing, repackaging, packaging, selling,
 1056 | delivery, holding, or offering for sale of any drug, device, or
 1057 | cosmetic for which the advertising or labeling is false or
 1058 | misleading.

1059 | (d) ~~(4)~~ The advertising of any drug, device, or cosmetic
 1060 | that is adulterated or misbranded.

PCB HCC 08-15

ORIGINAL

YEAR

1061 (e)~~(5)~~ The receiving in commerce of any drug, device, or
 1062 cosmetic that is falsely advertised or labeled or the delivering
 1063 or proffering for delivery of any such drug, device, or cosmetic.

1064 (f)~~(6)~~ The advertising or labeling of any product
 1065 containing ephedrine, a salt of ephedrine, an isomer of
 1066 ephedrine, or a salt of an isomer of ephedrine, for the
 1067 indication of stimulation, mental alertness, weight loss,
 1068 appetite control, energy, or other indications not approved by
 1069 the pertinent United States Food and Drug Administration Over-
 1070 the-Counter Final or Tentative Final Monograph or approved new
 1071 drug application under the federal act. In determining compliance
 1072 with this requirement, the department may consider the following
 1073 factors:

1074 1.~~(a)~~ The packaging of the product.

1075 2.~~(b)~~ The name and labeling of the product.

1076 3.~~(e)~~ The manner of distribution, advertising, and
 1077 promotion of the product, including verbal representations at the
 1078 point of sale.

1079 4.~~(d)~~ The duration, scope, and significance of abuse of the
 1080 particular product.

1081 (g)~~(7)~~—The advertising of any drug or device represented to
 1082 have any effect in any of the following conditions, disorders,
 1083 diseases, or processes:

1084 1.~~(a)~~ Blood disorders.

1085 2.~~(b)~~ Bone or joint diseases.

1086 3.~~(e)~~ Kidney diseases or disorders.

1087 4.~~(d)~~ Cancer.

1088 5.~~(e)~~ Diabetes.

1089 6.~~(f)~~ Gall bladder diseases or disorders.

PCB HCC 08-15

ORIGINAL

YEAR

- 1090 | 7.~~(g)~~ Heart and vascular diseases.
- 1091 | 8.~~(h)~~ High blood pressure.
- 1092 | 9.~~(i)~~ Diseases or disorders of the ear or auditory
- 1093 | apparatus, including hearing loss or deafness.
- 1094 | 10.~~(j)~~ Mental disease or mental retardation.
- 1095 | 11.~~(k)~~ Paralysis.
- 1096 | 12.~~(l)~~ Prostate gland disorders.
- 1097 | 13.~~(m)~~ Conditions of the scalp affecting hair loss.
- 1098 | 14.~~(n)~~ Baldness.
- 1099 | 15.~~(o)~~ Endocrine disorders.
- 1100 | 16.~~(p)~~ Sexual impotence.
- 1101 | 17.~~(q)~~ Tumors.
- 1102 | 18.~~(r)~~ Venereal diseases.
- 1103 | 19.~~(s)~~ Varicose ulcers.
- 1104 | 20.~~(t)~~ Breast enlargement.
- 1105 | 21.~~(u)~~ Purifying blood.
- 1106 | 22.~~(v)~~ Metabolic disorders.
- 1107 | 23.~~(w)~~ Immune system disorders or conditions affecting the
- 1108 | immune system.
- 1109 | 24.~~(x)~~ Extension of life expectancy.
- 1110 | 25.~~(y)~~ Stress and tension.
- 1111 | 26.~~(z)~~ Brain stimulation or performance.
- 1112 | 27.~~(aa)~~ The body's natural defense mechanisms.
- 1113 | 28.~~(bb)~~ Blood flow.
- 1114 | 29.~~(cc)~~ Depression.
- 1115 | 30.~~(dd)~~ Human immunodeficiency virus or acquired immune
- 1116 | deficiency syndrome or related disorders or conditions.

PCB HCC 08-15

ORIGINAL

YEAR

1117 (h)~~(8)~~ The representation or suggestion in labeling or
 1118 advertising that an article is approved under this part ~~ss.~~
 1119 ~~499.001-499.081~~, when such is not the case.

1120 (2) ~~499.0055 False or misleading advertisement.~~ In
 1121 determining whether an advertisement is false or misleading, the
 1122 department shall review the representations made or suggested by
 1123 statement, word, design, device, sound, or any combination
 1124 thereof within the advertisement and the extent to which the
 1125 advertisement fails to reveal material facts with respect to
 1126 consequences that can result from the use of the drug, device, or
 1127 cosmetic to which the advertisement relates under the conditions
 1128 of use prescribed in the labeling or advertisement.

1129 (3) (a) ~~499.0057 Advertisement exemptions.~~

1130 ~~(1)~~ An advertisement that is not prohibited under paragraph
 1131 (1) (a) ~~s. 499.0054(1)~~ is not prohibited under paragraph (1) (g) ~~s.~~
 1132 ~~499.0054(7)~~ if it is disseminated:

1133 1. To the public solely to advertise the product for those
 1134 indications that are safe and effective indications and the
 1135 product is safe and effective for self-medication, as established
 1136 by the United States Food and Drug Administration; or

1137 2. ~~if it is disseminated~~ Only to members of the medical,
 1138 dental, pharmaceutical, or veterinary professions or appears only
 1139 in the scientific periodicals of these professions.

1140 (b)~~(2)~~ Compliance with this part ~~ss. 499.001-499.081~~ and
 1141 the rules adopted under those sections creates no legal
 1142 presumption that a drug or device is safe or effective.

1143 Section 6. Section 499.006, Florida Statutes, is amended to
 1144 read:

PCB HCC 08-15

ORIGINAL

YEAR

1145 | 499.006 Adulterated drug or device.--A drug or device is
1146 | adulterated:

1147 | (1) If it consists in whole or in part of any filthy,
1148 | putrid, or decomposed substance;

1149 | (2) If it has been produced, prepared, packed, or held
1150 | under conditions whereby it could have been contaminated with
1151 | filth or rendered injurious to health;

1152 | (3) If it is a drug and the methods used in, or the
1153 | facilities or controls used for, its manufacture, processing,
1154 | packing, or holding do not conform to, or are not operated or
1155 | administered in conformity with, current good manufacturing
1156 | practices to assure that the drug meets the requirements of this
1157 | part ~~ss. 499.001-499.081~~ and that the drug has the identity and
1158 | strength, and meets the standard of quality and purity, which it
1159 | purports or is represented to possess;

1160 | (4) If it is a drug and its container is composed, in whole
1161 | or in part, of any poisonous or deleterious substance which could
1162 | render the contents injurious to health;

1163 | (5) If it is a drug and it bears or contains, for the
1164 | purpose of coloring only, a color additive that is unsafe within
1165 | the meaning of the federal act; or, if it is a color additive,
1166 | the intended use of which in or on drugs is for the purpose of
1167 | coloring only, and it is unsafe within the meaning of the federal
1168 | act;

1169 | (6) If it purports to be, or is represented as, a drug the
1170 | name of which is recognized in the official compendium, and its
1171 | strength differs from, or its quality or purity falls below, the
1172 | standard set forth in such compendium. The determination as to
1173 | strength, quality, or purity must be made in accordance with the

PCB HCC 08-15

ORIGINAL

YEAR

1174 tests or methods of assay set forth in such compendium, or, when
 1175 such tests or methods of assay are absent or inadequate, in
 1176 accordance with those tests or methods of assay prescribed under
 1177 authority of the federal act. A drug defined in the official
 1178 compendium is not adulterated under this subsection merely
 1179 because it differs from the standard of strength, quality, or
 1180 purity set forth for that drug in such compendium if its
 1181 difference in strength, quality, or purity from such standard is
 1182 plainly stated on its label;

1183 (7) If it is not subject to subsection (6) and its strength
 1184 differs from, or its purity or quality falls below the standard
 1185 of, that which it purports or is represented to possess;

1186 (8) If it is a drug:

1187 (a) With which any substance has been mixed or packed so as
 1188 to reduce the quality or strength of the drug; or

1189 (b) For which any substance has been substituted wholly or
 1190 in part;

1191 (9) If it is a drug or device for which the expiration date
 1192 has passed;

1193 (10) If it is a prescription ~~legend~~ drug for which the
 1194 required pedigree paper is nonexistent, fraudulent, or incomplete
 1195 under the requirements of this part ~~ss. 499.001-499.081~~ or
 1196 applicable rules, or that has been purchased, held, sold, or
 1197 distributed at any time by a person not authorized under federal
 1198 or state law to do so; or

1199 (11) If it is a prescription drug subject to, defined by,
 1200 or described by s. 503(b) of the Federal Food, Drug, and Cosmetic
 1201 Act which has been returned by a veterinarian to a limited
 1202 prescription drug veterinary wholesaler.

PCB HCC 08-15

ORIGINAL

YEAR

1203 Section 7. Section 499.007, Florida Statutes, is amended to
 1204 read:

1205 499.007 Misbranded drug or device.--A drug or device is
 1206 misbranded:

1207 (1) If its labeling is in any way false or misleading.

1208 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
 1209 label containing:

1210 (a) The name and place of business of the manufacturer,
 1211 repackager, or distributor of the finished dosage form of the
 1212 drug. For the purpose of this paragraph, the finished dosage form
 1213 of a prescription medicinal ~~medicinal~~ drug is that form of the drug which
 1214 is, or is intended to be, dispensed or administered to the
 1215 patient and requires no further manufacturing or processing other
 1216 than packaging, reconstitution, and labeling; and

1217 (b) An accurate statement of the quantity of the contents
 1218 in terms of weight, measure, or numerical count. ~~;~~ However, under
 1219 this section, reasonable variations are permitted, and the
 1220 department shall establish by rule exemptions for small packages.

1221 (3) If it is an active pharmaceutical ingredient in bulk
 1222 form, and does not bear a label containing:

1223 (a) the name and place of business of the manufacturer,
 1224 repackager or distributor; and

1225 (b) an accurate statement of the quantity of the contents in
 1226 terms of weight, measure, or numerical count.

1227 (4) ~~(3)~~ If any word, statement, or other information
 1228 required by or under this part ~~ss. 499.001-499.081~~ to appear on
 1229 the label or labeling is not prominently placed thereon with such
 1230 conspicuousness as compared with other words, statements,
 1231 designs, or devices in the labeling, and in such terms, as to

PCB HCC 08-15

ORIGINAL

YEAR

1232 render the word, statement, or other information likely to be
 1233 read and understood under customary conditions of purchase and
 1234 use.

1235 (5)~~(4)~~ If it is a drug and is not designated solely by a
 1236 name recognized in an official compendium and ~~, unless~~ its label
 1237 does not bear ~~bears~~:

1238 (a) The common or usual name of the drug, if any; and

1239 (b) In case it is fabricated from two or more ingredients,
 1240 the common or usual name and quantity of each active ingredient.

1241 (6)~~(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

1242 (a) Adequate directions for use; and

1243 (b) Adequate warnings against use in those pathological
 1244 conditions in which its use may be dangerous to health or against
 1245 use by children if its use may be dangerous to health, or against
 1246 unsafe dosage or methods or duration of administration or
 1247 application, in such manner and form as are necessary for the
 1248 protection of users.

1249 (7)~~(6)~~ If it purports to be a drug the name of which is
 1250 recognized in the official compendium and it ~~, unless it is not~~
 1251 packaged and labeled as prescribed therein. ~~+~~ However, the method
 1252 of packaging may be modified with the consent of the department.

1253 (8)~~(7)~~ If it has been found by the department to be a drug
 1254 liable to deterioration and it ~~, unless it is not~~ packaged in
 1255 such form and manner, and its label bears a statement of such
 1256 precautions, as the department by rule requires as necessary to
 1257 protect the public health. Such rule may not be established for
 1258 any drug recognized in an official compendium until the
 1259 department has informed the appropriate body charged with the
 1260 revision of such compendium of the need for such packaging or

PCB HCC 08-15

ORIGINAL

YEAR

1261 labeling requirements and that body has failed within a
 1262 reasonable time to prescribe such requirements.
 1263 (9)~~(8)~~ If it is:
 1264 (a) A drug and its container or finished dosage form is so
 1265 made, formed, or filled as to be misleading;
 1266 (b) An imitation of another drug; or
 1267 (c) Offered for sale under the name of another drug.
 1268 (10)~~(9)~~ If it is dangerous to health when used in the
 1269 dosage or with the frequency or duration prescribed, recommended,
 1270 or suggested in the labeling of the drug.
 1271 (11)~~(10)~~ If it is, purports to be, or is represented as a
 1272 drug composed wholly or partly of insulin and it ~~, unless:~~
 1273 ~~(a)~~—It is not from a batch with respect to which a
 1274 certificate has been issued pursuant to s. 506 of the federal
 1275 act, which ~~, and~~
 1276 ~~(b)~~—The certificate is in effect with respect to the drug.
 1277 (12)~~(11)~~ If it is, purports to be, or is represented as a
 1278 drug composed wholly or partly of any kind of antibiotic
 1279 requiring certification under the federal act and ~~unless:~~
 1280 ~~(a)~~—it is not from a batch with respect to which a
 1281 certificate has been issued pursuant to s. 507 of the federal
 1282 act, which ~~, and~~
 1283 ~~(b)~~—The certificate is in effect with respect to the drug.
 1284 †
 1285
 1286 However, this subsection does not apply to any drug or class of
 1287 drugs exempted by regulations adopted under s. 507(c) or (d) of
 1288 the federal act.

PCB HCC 08-15

ORIGINAL

YEAR

1289 (13)~~(12)~~ If it is a drug intended for use by humans which
 1290 is a habit-forming drug or which, because of its toxicity or
 1291 other potentiality for harmful effect, or the method of its use,
 1292 or the collateral measures necessary to its use, is not safe for
 1293 use except under the supervision of a practitioner licensed by
 1294 law to administer such drugs, —or which is limited by an
 1295 effective application under s. 505 of the federal act to use
 1296 under the professional supervision of a practitioner licensed by
 1297 law to prescribe such drug, if ~~unless~~ it is not dispensed only:

1298 (a) Upon the written prescription of a practitioner
 1299 licensed by law to prescribe such drug;

1300 (b) Upon an oral prescription of such practitioner, which
 1301 is reduced promptly to writing and filled by the pharmacist; or

1302 (c) By refilling any such written or oral prescription, if
 1303 such refilling is authorized by the prescriber either in the
 1304 original prescription or by oral order which is reduced promptly
 1305 to writing and filled by the pharmacist.

1306
 1307 This subsection does not relieve any person from any requirement
 1308 prescribed by law with respect to controlled substances as
 1309 defined in the applicable federal and state laws.

1310 (14)~~(13)~~ If it is a drug that is subject to paragraph
 1311 (13)~~(12)~~(a), and if, at any time before it is dispensed, its
 1312 label does not ~~fails to~~ bear the statement:

1313 (a) "Caution: Federal Law Prohibits Dispensing Without
 1314 Prescription";

1315 (b) "Rx Only";

1316 (c) The prescription symbol followed by the word "Only"; or

PCB HCC 08-15

ORIGINAL

YEAR

1317 (d) "Caution: State Law Prohibits Dispensing Without
1318 Prescription."

1319 ~~(15)-(14)~~ If it is a drug that is not subject to paragraph
1320 ~~(13)-(12)~~(a), if at any time before it is dispensed its label
1321 bears the statement of caution required in subsection ~~(14)-(13)~~.

1322 ~~(16)-(15)~~ If it is a color additive, the intended use of
1323 which in or on drugs is for the purpose of coloring only and ~~7~~
1324 ~~unless~~ its packaging and labeling are not in conformity with the
1325 packaging and labeling requirements that apply to such color
1326 additive and are prescribed under the federal act.

1327 (17) A drug dispensed by filling or refilling a written or
1328 oral prescription of a practitioner licensed by law to prescribe
1329 such drug is exempt from the requirements of this section, except
1330 subsections (1), ~~(9)-(8)~~, ~~(11)-(10)~~, and ~~(12)-(11)~~ and the packaging
1331 requirements of subsections ~~(7)-(6)~~ and ~~(8)-(7)~~, if the drug bears
1332 a label that contains the name and address of the dispenser or
1333 seller, the prescription number and the date the prescription was
1334 written or filled, the name of the prescriber and the name of the
1335 patient, and the directions for use and cautionary statements.
1336 This exemption does not apply to any drug dispensed in the course
1337 of the conduct of a business of dispensing drugs pursuant to
1338 diagnosis by mail or to any drug dispensed in violation of
1339 subsection ~~(13)-(12)~~. The department may, by rule, exempt drugs
1340 subject to ss. 499.062-499.064 from subsection ~~(13)-(12)~~ if
1341 compliance with that subsection is not necessary to protect the
1342 public health, safety, and welfare.

1343 Section 8. Section 499.008, Florida Statutes, is amended to
1344 read:

1345 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

PCB HCC 08-15

ORIGINAL

YEAR

1346 (1) If it bears or contains any poisonous or deleterious
 1347 substance that is injurious to users under the conditions of use
 1348 prescribed in the labeling or advertisement thereof or under such
 1349 conditions of use as are customary or usual. ~~;~~ However, this
 1350 subsection does not apply to coal-tar hair dye:

1351 (a) The label of which bears the following legend
 1352 conspicuously displayed thereon: "Caution: This product contains
 1353 ingredients which may cause skin irritation on certain
 1354 individuals, and a preliminary test according to accompanying
 1355 directions should first be made. This product must not be used
 1356 for dyeing the eyelashes or eyebrows; to do so may cause
 1357 blindness"; and

1358 (b) The labeling of which bears adequate directions for
 1359 such preliminary testing.

1360

1361 ~~For the purposes of this subsection and subsection (4), the term~~
 1362 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1363 (2) If it consists in whole or in part of any filthy,
 1364 putrid, or decomposed substance.

1365 (3) If it has been produced, prepared, packed, or held
 1366 under conditions whereby it could have become contaminated with
 1367 filth or whereby it could have been rendered injurious to health.

1368 (4) If it is not a hair dye and it is, or it bears or
 1369 contains, a color additive that is unsafe within the meaning of
 1370 the federal act.

1371 (5) For the purposes of subsections (1) and (4), the term
 1372 "hair dye" does not include eyelash dyes or eyebrow dyes.

1373 Section 9. Section 499.009, Florida Statutes, is amended to
 1374 read:

PCB HCC 08-15

ORIGINAL

YEAR

1375 | 499.009 Misbranded cosmetics.--A cosmetic is misbranded:
 1376 | (1) If its labeling is false or misleading in any
 1377 | particular.
 1378 | (2) ~~Unless,~~If in package form, it does not bear ~~bears~~ a
 1379 | label containing:
 1380 | (a) The name and place of business of the manufacturer,
 1381 | packer, or distributor;
 1382 | (b) An accurate statement of the quantity of the contents
 1383 | in terms of weight, measure, or numerical count; however, under
 1384 | this paragraph reasonable variations are permitted, and the
 1385 | department shall establish by rule exemptions for small packages;
 1386 | and
 1387 | (c) A declaration of ingredients in descending order of
 1388 | predominance, or as otherwise required by federal law.
 1389 | (3) If any word, statement, or other information required
 1390 | by or under authority of this part ~~ss. 499.001-499.081~~ to appear
 1391 | on the label or labeling is not prominently placed thereon with
 1392 | such conspicuousness as compared with other words, statements,
 1393 | designs, or devices in the labeling, and in such terms, as to
 1394 | render the word, statement, or other information likely to be
 1395 | read and understood by an individual under customary conditions
 1396 | of purchase and use.
 1397 | (4) If its container is so made, formed, or filled as to be
 1398 | misleading.
 1399 | (5) ~~Unless,~~If it is a color additive, its packaging and
 1400 | labeling are not in conformity with the packaging and labeling
 1401 | requirements applicable to that color additive prescribed under
 1402 | the federal act. This subsection does not apply to packages of

PCB HCC 08-15

ORIGINAL

YEAR

1403 color additives that, with respect to their use for cosmetics,
 1404 are marketed and intended for use only in or on hair dyes.

1405 Section 10. Section 499.01, Florida Statutes, is amended,
 1406 subsection (2) and paragraphs (2)(a)-(h) of section 499.012,
 1407 Florida Statutes, are renumbered as subsection (2) and paragraphs
 1408 (2)(d), (n), (e), (f), (c), (i), (k), and (l) of that section and
 1409 amended, paragraphs (2)(b)-(e) of section 499.013, Florida
 1410 Statutes, are renumbered as paragraphs (2)(f), (o), (q), and (r)
 1411 of that section and amended, and section 499.014, Florida
 1412 Statutes, is renumbered as paragraph (2)(g) of that section and
 1413 amended, to read:

1414 499.01 ~~Permits; applications; renewal; general~~
 1415 ~~requirements.~~--

1416 (1) Prior to operating, a permit is required for each
 1417 person and establishment that intends to operate as:

- 1418 (a) A prescription drug manufacturer;
- 1419 (b) A prescription drug repackager;
- 1420 (c) A nonresident prescription drug manufacturer;
- 1421 (d) A prescription drug wholesale distributor;
- 1422 (e) An out-of-state prescription drug wholesale
 1423 distributor;
- 1424 (f) A retail pharmacy drug wholesale distributor;
- 1425 (g) A restricted prescription drug distributor;
- 1426 (h) A complimentary drug distributor;
- 1427 (i) A freight forwarder;
- 1428 (j) A veterinary prescription drug retail establishment;
- 1429 (k) A veterinary prescription drug wholesale distributor;
- 1430 (l) A limited prescription drug veterinary wholesale
 1431 distributor;

PCB HCC 08-15

ORIGINAL

YEAR

- 1432 (m) A medical oxygen retail establishment;
- 1433 (n) A compressed medical gas wholesale distributor;
- 1434 (o) A compressed medical gas manufacturer;
- 1435 (p)~~(e)~~ An over-the-counter drug manufacturer;
- 1436 ~~(d) A compressed medical gas manufacturer;~~
- 1437 (q)~~(e)~~ A device manufacturer; or
- 1438 (r)~~(f)~~ A cosmetic manufacturer. †
- 1439 ~~(g) A prescription drug wholesaler;~~
- 1440 ~~(h) A veterinary prescription drug wholesaler;~~
- 1441 ~~(i) A compressed medical gas wholesaler;~~
- 1442 ~~(j) An out-of-state prescription drug wholesaler;~~
- 1443 ~~(k) A nonresident prescription drug manufacturer;~~
- 1444 ~~(l) A freight forwarder;~~
- 1445 ~~(m) A retail pharmacy drug wholesaler;~~
- 1446 ~~(n) A veterinary legend drug retail establishment;~~
- 1447 ~~(o) A medical oxygen retail establishment;~~
- 1448 ~~(p) A complimentary drug distributor;~~
- 1449 ~~(q) A restricted prescription drug distributor; or~~
- 1450 ~~(r) A limited prescription drug veterinary wholesaler.~~
- 1451 (2) The following ~~types of wholesaler~~ permits are
- 1452 established:
- 1453 (a) Prescription drug manufacturer permit.--A prescription
- 1454 drug manufacturer permit is required for any person that
- 1455 manufactures a prescription drug in this state.
- 1456 1. A person that operates an establishment permitted as a
- 1457 prescription drug manufacturer may engage in wholesale
- 1458 distribution of prescription drugs manufactured at that
- 1459 establishment and must comply with all the provisions of this

PCB HCC 08-15

ORIGINAL

YEAR

1460 part and the rules adopted under those sections that apply to a
 1461 wholesale distributor.

1462 2. A prescription drug manufacturer must comply with all
 1463 appropriate state and federal good manufacturing practices.

1464 (b) Prescription drug repackager permit.--A prescription
 1465 drug repackager permit is required for any person that repackages
 1466 a prescription drug in this state.

1467 1. A person that operates an establishment permitted as a
 1468 prescription drug repackager may engage in wholesale distribution
 1469 of prescription drugs repackaged at that establishment and must
 1470 comply with all the provisions of this part and the rules adopted
 1471 under those sections that apply to a wholesale distributor.

1472 2. A prescription drug repackager must comply with all
 1473 appropriate state and federal good manufacturing practices.

1474 (c)-(e) Nonresident prescription drug manufacturer permit.--
 1475 A nonresident prescription drug manufacturer permit is required
 1476 for any person that is a manufacturer of prescription drugs, or
 1477 the distribution point for a manufacturer of prescription drugs,
 1478 and located outside of this state, or that is an entity to whom
 1479 an approved new drug application has been issued by the United
 1480 States Food and Drug Administration, or the contracted
 1481 manufacturer of the approved new drug application holder, and
 1482 located outside the United States, which engages in the wholesale
 1483 distribution in this state of the prescription drugs it
 1484 manufactures or is responsible for manufacturing. Each such
 1485 manufacturer or entity must be permitted by the department and
 1486 comply with all the provisions required of a wholesale
 1487 distributor under this part ~~ss. 499.001-499.081~~, except s.
 1488 499.012111-(6)-(d).

PCB HCC 08-15

ORIGINAL

YEAR

1489 | 1. A person that distributes prescription drugs that it did
 1490 | not manufacture must also obtain an out-of-state prescription
 1491 | drug wholesale distributor ~~wholesaler~~ permit pursuant to this
 1492 | section to engage in the wholesale distribution of the
 1493 | prescription drugs manufactured by another person and comply with
 1494 | the requirements of an out-of-state prescription drug wholesale
 1495 | distributor ~~wholesaler~~.

1496 | 2. Any such person must comply with the licensing or
 1497 | permitting requirements of the jurisdiction in which the
 1498 | establishment is located and the federal act, and any product
 1499 | wholesaled into this state must comply with this part ~~ss.~~
 1500 | ~~499.001-499.081~~. If a person intends to import prescription drugs
 1501 | from a foreign country into this state, the nonresident
 1502 | prescription drug manufacturer must provide to the department a
 1503 | list identifying each prescription drug it intends to import and
 1504 | document approval by the United States Food and Drug
 1505 | Administration for such importation.

1506 | (d)~~(a)~~ A prescription drug wholesale distributor
 1507 | ~~wholesaler's~~ permit.--A prescription drug wholesale distributor
 1508 | ~~wholesaler~~ is a wholesale distributor that may engage in the
 1509 | wholesale distribution of prescription drugs. A prescription drug
 1510 | wholesale distributor ~~wholesaler~~ that applies to the department
 1511 | for a new permit or the renewal of a permit must submit a bond of
 1512 | \$100,000, or other equivalent means of security acceptable to the
 1513 | department, such as an irrevocable letter of credit or a deposit
 1514 | in a trust account or financial institution, payable to the
 1515 | Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the
 1516 | bond is to secure payment of any administrative penalties imposed
 1517 | by the department and any fees and costs incurred by the

PCB HCC 08-15

ORIGINAL

YEAR

1518 department regarding that permit which are authorized under state
 1519 law and which the permittee fails to pay 30 days after the fine
 1520 or costs become final. The department may make a claim against
 1521 such bond or security until 1 year after the permittee's license
 1522 ceases to be valid or until 60 days after any administrative or
 1523 legal proceeding authorized in this part that involves the
 1524 permittee is concluded, including any appeal, whichever occurs
 1525 later. The department may adopt rules for issuing a prescription
 1526 drug wholesale distributor ~~wholesaler~~-broker permit to a person
 1527 who engages in the wholesale distribution of prescription drugs
 1528 and does not take physical possession of any prescription drugs.
 1529 (e) ~~(e)~~ An out-of-state prescription drug wholesale
 1530 distributor ~~wholesaler's~~ permit.--An out-of-state prescription
 1531 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor
 1532 located outside this state which engages in the wholesale
 1533 distribution of prescription drugs into this state and which must
 1534 be permitted by the department and comply with all the provisions
 1535 required of a wholesale distributor under this part ~~ss. 499.001-~~
 1536 ~~499.081~~. An out-of-state prescription drug wholesale distributor
 1537 ~~wholesaler~~ that applies to the department for a new permit or the
 1538 renewal of a permit must submit a bond of \$100,000, or other
 1539 equivalent means of security acceptable to the department, such
 1540 as an irrevocable letter of credit or a deposit in a trust
 1541 account or financial institution, payable to the Florida Drug,
 1542 Device, and Cosmetic Trust Fund. The purpose of the bond is to
 1543 secure payment of any administrative penalties imposed by the
 1544 department and any fees and costs incurred by the department
 1545 regarding that permit which are authorized under state law and
 1546 which the permittee fails to pay 30 days after the fine or costs

PCB HCC 08-15

ORIGINAL

YEAR

1547 | become final. The department may make a claim against such bond
 1548 | or security until 1 year after the permittee's license ceases to
 1549 | be valid or until 60 days after any administrative or legal
 1550 | proceeding authorized in this part that involves the permittee is
 1551 | concluded, including any appeal, whichever occurs later.

1552 | 1. The out-of-state prescription drug wholesale distributor
 1553 | ~~wholesaler~~ must maintain at all times a license or permit to
 1554 | engage in the wholesale distribution of prescription drugs in
 1555 | compliance with laws of the state in which it is a resident.

1556 | 2. An out-of-state prescription drug wholesale distributor
 1557 | ~~wholesaler's~~ permit is not required for an intracompany sale or
 1558 | transfer of a prescription drug from an out-of-state
 1559 | establishment that is duly licensed as a prescription drug
 1560 | wholesale distributor ~~wholesaler~~, in its state of residence, to a
 1561 | licensed prescription drug wholesale distributor ~~wholesaler~~ in
 1562 | this state, if both wholesale distributor ~~wholesalers~~ conduct
 1563 | wholesale distributions of prescription drugs under the same
 1564 | business name. The recordkeeping requirements of ss. s-
 1565 | 499.0121(6) and 499.012111 must be followed for this transaction.

1566 | (f) ~~(d)~~ A retail pharmacy wholesale distributor ~~wholesaler's~~
 1567 | permit.--A retail pharmacy wholesale distributor ~~wholesaler~~ is a
 1568 | retail pharmacy engaged in wholesale distribution of prescription
 1569 | drugs within this state under the following conditions:

1570 | 1. The pharmacy must obtain a retail pharmacy wholesale
 1571 | distributor ~~wholesaler's~~ permit pursuant to this part ss-
 1572 | ~~499.001-499.081~~ and the rules adopted under those sections.

1573 | 2. The wholesale distribution activity does not exceed 30
 1574 | percent of the total annual purchases of prescription drugs. If
 1575 | the wholesale distribution activity exceeds the 30-percent

PCB HCC 08-15

ORIGINAL

YEAR

1576 maximum, the pharmacy must obtain a prescription drug wholesale
 1577 distributor ~~wholesaler's~~ permit.

1578 3. The transfer of prescription drugs that appear in any
 1579 schedule contained in chapter 893 is subject to chapter 893 and
 1580 the federal Comprehensive Drug Abuse Prevention and Control Act
 1581 of 1970.

1582 4. The transfer is between a retail pharmacy and another
 1583 retail pharmacy, or a Modified Class II institutional pharmacy,
 1584 or a health care practitioner licensed in this state and
 1585 authorized by law to dispense or prescribe prescription drugs.

1586 5. All records of sales of prescription drugs subject to
 1587 this section must be maintained separate and distinct from other
 1588 records and comply with the recordkeeping requirements of this
 1589 part ~~ss. 499.001-499.081~~.

1590 (g) Restricted prescription drug distributor permit.--
 1591 ~~499.014 Distribution of legend drugs by hospitals, health care~~
 1592 ~~entities, charitable organizations, and return or destruction~~
 1593 ~~companies; permits, general requirements.—~~

1594 ~~(1)~~—A restricted prescription drug distributor permit is
 1595 required for any person that engages in the distribution of a
 1596 prescription legend drug, which distribution is not considered
 1597 "wholesale distribution" under s. 499.003(55)(a)~~012(1)(a)~~1.

1598 1.(2) A person who engages in the receipt or distribution
 1599 of a prescription drug in this state for the purpose of
 1600 processing its return or its destruction must obtain a permit as
 1601 a restricted prescription drug distributor if such person is not
 1602 the person initiating the return, the prescription drug wholesale
 1603 supplier of the person initiating the return, or the manufacturer
 1604 of the drug.

PCB HCC 08-15

ORIGINAL

YEAR

1605 | ~~2.(3)~~ Storage, handling, and recordkeeping of these
 1606 | distributions must comply with the requirements for wholesale
 1607 | distributors under s. 499.0121, except those set forth in s.
 1608 | 499.0121~~11(6)(d)~~.

1609 | ~~3.(4)~~ A person who applies for a permit as a restricted
 1610 | prescription drug distributor, or for the renewal of such a
 1611 | permit, must provide to the department the information required
 1612 | under s. 499.012.

1613 | ~~4.(5)~~ The department ~~may issue permits to restricted~~
 1614 | ~~prescription drug distributors and~~ may adopt rules regarding the
 1615 | distribution of prescription drugs by hospitals, health care
 1616 | entities, charitable organizations, or other persons not involved
 1617 | in wholesale distribution, which rules are necessary for the
 1618 | protection of the public health, safety, and welfare.

1619 | (h) Complimentary drug distributor permit.--A complimentary
 1620 | drug distributor permit is required for any person that engages
 1621 | in the distribution of a complimentary drug, subject to the
 1622 | requirements of s. 499.028.

1623 | (i)~~(f)~~ Freight forwarder permit.--A freight forwarder
 1624 | permit is required for any person that engages in the
 1625 | distribution of a prescription ~~legend~~ drug as a freight forwarder
 1626 | unless the person is a common carrier. The storage, handling, and
 1627 | recordkeeping of such distributions must comply with the
 1628 | requirements for wholesale distributors under s. 499.0121, except
 1629 | those set forth in s. 499.0121~~11(6)(d)~~. A freight forwarder must
 1630 | provide the source of the prescription ~~legend~~ drugs with a
 1631 | validated airway bill, bill of lading, or other appropriate
 1632 | documentation to evidence the exportation of the product.

PCB HCC 08-15

ORIGINAL

YEAR

1633 (j) Veterinary prescription drug retail establishment
 1634 permit.--A veterinary prescription drug retail establishment
 1635 permit is required for any person that sells veterinary
 1636 prescription drugs to the public, but does not include a pharmacy
 1637 licensed under chapter 465.

1638 1. The sale to the public must be based on a valid written
 1639 order from a veterinarian licensed in this state who has a valid
 1640 client-veterinarian relationship with the purchaser's animal.

1641 2. Veterinary prescription drugs may not be sold in excess
 1642 of the amount clearly indicated on the order or beyond the date
 1643 indicated on the order.

1644 3. An order may not be valid for more than one year.

1645 4. A veterinary prescription drug retail establishment may
 1646 not purchase, sell, trade, or possess human prescription drugs or
 1647 any controlled substance as defined in chapter 893.

1648 5. A veterinary prescription drug retail establishment must
 1649 sell a veterinary prescription drug in the original, sealed
 1650 manufacturer's container with all labeling intact and legible.
 1651 The department may adopt by rule additional labeling requirements
 1652 for the sale of a veterinary prescription drug.

1653 6. A veterinary prescription drug retail establishment must
 1654 comply with all of the wholesale distribution requirements of s.
 1655 499.0121.

1656 7. Prescription drugs sold by a veterinary prescription
 1657 drug retail establishment pursuant to a practitioner's order may
 1658 not be returned into the retail establishment's inventory.

1659 (k)(g) A veterinary prescription drug wholesale distributor
 1660 ~~wholesaler~~ permit.--A veterinary prescription drug wholesale
 1661 distributor ~~wholesaler~~ permit is required for any person that

PCB HCC 08-15

ORIGINAL

YEAR

1662 engages in the distribution of veterinary prescription drugs in
 1663 or into this state. A veterinary prescription drug wholesale
 1664 distributor ~~wholesaler~~ that also distributes prescription drugs
 1665 subject to, defined by, or described by s. 503(b) of the Federal
 1666 Food, Drug, and Cosmetic Act which it did not manufacture must
 1667 obtain a permit as a prescription drug wholesale distributor
 1668 ~~wholesaler~~, an out-of-state prescription drug wholesale
 1669 distributor ~~wholesaler~~, or a limited prescription drug veterinary
 1670 wholesale distributor ~~wholesaler~~ in lieu of the veterinary
 1671 prescription drug wholesale distributor ~~wholesaler~~ permit. A
 1672 veterinary prescription drug wholesale distributor ~~wholesaler~~
 1673 must comply with the requirements for wholesale distributors
 1674 under s. 499.0121, except those set forth in s. 499.012111(6)(d).
 1675 (1)(h) Limited prescription drug veterinary wholesale
 1676 distributor ~~wholesaler~~ permit.--Unless engaging in the activities
 1677 of and permitted as a prescription drug manufacturer, nonresident
 1678 prescription drug manufacturer, prescription drug wholesale
 1679 distributor ~~wholesaler~~, or out-of-state prescription drug
 1680 wholesale distributor ~~wholesaler~~, a limited prescription drug
 1681 veterinary wholesale distributor ~~wholesaler~~ permit is required
 1682 for any person that engages in the distribution in or into this
 1683 state of veterinary prescription drugs and prescription drugs
 1684 subject to, defined by, or described by s. 503(b) of the Federal
 1685 Food, Drug, and Cosmetic Act under the following conditions:
 1686 1. The person is engaged in the business of wholesaling
 1687 prescription and veterinary prescription drugs to persons:
 1688 a. Licensed as veterinarians practicing on a full-time
 1689 basis;

PCB HCC 08-15

ORIGINAL

YEAR

1690 b. Regularly and lawfully engaged in instruction in
 1691 veterinary medicine;
 1692 c. Regularly and lawfully engaged in law enforcement
 1693 activities;
 1694 d. For use in research not involving clinical use; or
 1695 e. For use in chemical analysis or physical testing or for
 1696 purposes of instruction in law enforcement activities, research,
 1697 or testing.

1698 2. No more than 30 percent of total annual prescription
 1699 drug sales may be prescription drugs approved for human use which
 1700 are subject to, defined by, or described by s. 503(b) of the
 1701 Federal Food, Drug, and Cosmetic Act.

1702 3. The person does not distribute ~~is not permitted,~~
 1703 ~~licensed, or otherwise authorized~~ in any jurisdiction state ~~to~~
 1704 ~~wholesale~~ prescription drugs subject to, defined by, or described
 1705 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any
 1706 person who is authorized to sell, distribute, purchase, trade, or
 1707 use these drugs on or for humans.

1708 4. A limited prescription drug veterinary wholesale
 1709 distributor ~~wholesaler~~ that applies to the department for a new
 1710 permit or the renewal of a permit must submit a bond of \$20,000,
 1711 or other equivalent means of security acceptable to the
 1712 department, such as an irrevocable letter of credit or a deposit
 1713 in a trust account or financial institution, payable to the
 1714 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the
 1715 bond is to secure payment of any administrative penalties imposed
 1716 by the department and any fees and costs incurred by the
 1717 department regarding that permit which are authorized under state
 1718 law and which the permittee fails to pay 30 days after the fine

PCB HCC 08-15

ORIGINAL

YEAR

1719 or costs become final. The department may make a claim against
 1720 such bond or security until 1 year after the permittee's license
 1721 ceases to be valid or until 60 days after any administrative or
 1722 legal proceeding authorized in this part that ss. 499.001-499.081
 1723 ~~which~~ involves the permittee is concluded, including any appeal,
 1724 whichever occurs later.

1725 5. A limited prescription drug veterinary wholesale
 1726 distributor ~~wholesaler~~ must maintain at all times a license or
 1727 permit to engage in the wholesale distribution of prescription
 1728 drugs in compliance with laws of the state in which it is a
 1729 resident.

1730 6. A limited prescription drug veterinary wholesale
 1731 distributor ~~wholesaler~~ must comply with the requirements for
 1732 wholesale distributors under s. 499.0121, except that a limited
 1733 prescription drug veterinary wholesale distributor ~~wholesaler~~ is
 1734 not required to provide a pedigree paper as required by s.
 1735 499.0121~~11(6)(d)~~ upon the wholesale distribution of a
 1736 prescription drug to a veterinarian.

1737 7. A limited prescription drug veterinary wholesale
 1738 distributor ~~wholesaler~~ may not return to inventory for subsequent
 1739 wholesale distribution any prescription drug subject to, defined
 1740 by, or described by s. 503(b) of the Federal Food, Drug, and
 1741 Cosmetic Act which has been returned by a veterinarian.

1742 8. ~~An out-of-state prescription drug wholesaler's permit or~~
 1743 A limited prescription drug veterinary wholesale distributor
 1744 ~~wholesaler~~ permit is not required for an intracompany sale or
 1745 transfer of a prescription drug from an out-of-state
 1746 establishment that is duly licensed to engage in the wholesale
 1747 distribution of prescription drugs in its state of residence to a

PCB HCC 08-15

ORIGINAL

YEAR

1748 licensed limited prescription drug veterinary wholesale
 1749 distributor ~~wholesaler~~ in this state if both wholesale
 1750 distributors conduct wholesale distributions of prescription
 1751 drugs under the same business name. The recordkeeping
 1752 requirements of ss. s. 499.0121(6) and 499.012111 must be
 1753 followed for this transaction.

1754 (m) Medical oxygen retail establishment permit.--A medical
 1755 oxygen retail establishment permit is required for any person
 1756 that sells medical oxygen to patients only. The sale must be
 1757 based on an order from a practitioner authorized by law to
 1758 prescribe. The term does not include a pharmacy licensed under
 1759 chapter 465.

1760 1. A medical oxygen retail establishment may not possess,
 1761 purchase, sell, or trade any prescription drug other than medical
 1762 oxygen.

1763 2. A medical oxygen retail establishment may refill medical
 1764 oxygen for an individual patient based on an order from a
 1765 practitioner authorized by law to prescribe. A medical oxygen
 1766 retail establishment that refills medical oxygen must comply with
 1767 all appropriate state and federal good manufacturing practices.

1768 3. A medical oxygen retail establishment must comply with
 1769 all of the wholesale distribution requirements of s. 499.0121.

1770 4. Prescription medical oxygen sold by a medical oxygen
 1771 retail establishment pursuant to a practitioner's order may not
 1772 be returned into the retail establishment's inventory.

1773 (n) ~~(b)~~ A compressed medical gas wholesale distributor
 1774 ~~wholesaler's~~ permit.--A compressed medical gas wholesale
 1775 distributor ~~wholesaler~~ is a wholesale distributor that is limited
 1776 to the wholesale distribution of compressed medical gases to

PCB HCC 08-15

ORIGINAL

YEAR

1777 other than the consumer or patient. The compressed medical gas
 1778 must be in the original sealed container that was purchased by
 1779 that wholesale distributor ~~wholesaler~~. A compressed medical gas
 1780 wholesale distributor ~~wholesaler~~ may not possess or engage in the
 1781 wholesale distribution of any prescription drug other than
 1782 compressed medical gases. The department shall adopt rules that
 1783 govern the wholesale distribution of prescription medical oxygen
 1784 for emergency use. With respect to the emergency use of
 1785 prescription medical oxygen, those rules may not be inconsistent
 1786 with rules and regulations of federal agencies unless the
 1787 Legislature specifically directs otherwise.

1788 (o) Compressed medical gas manufacturer permit. ~~(e)~~ A
 1789 compressed medical gas manufacturer ~~manufacturer's~~ permit is
 1790 required for any person that engages in the manufacture of
 1791 compressed medical gases or repackages compressed medical gases
 1792 from one container to another.

1793 1. A compressed medical gas manufacturer ~~permittee~~ may not
 1794 manufacture or possess any prescription drug other than
 1795 compressed medical gases.

1796 2. A compressed medical gas manufacturer ~~permittee~~ may
 1797 engage in wholesale distribution of compressed medical gases
 1798 manufactured at that establishment and must comply with all the
 1799 provisions of this part ~~ss. 499.001-499.001~~ and the rules adopted
 1800 under those sections that apply to a wholesale distributor.

1801 3. A compressed medical gas manufacturer ~~permittee~~ must
 1802 comply with all appropriate state and federal good manufacturing
 1803 practices.

1804 (p) Over-the-counter drug manufacturer permit. ~~(b)~~ An
 1805 over-the-counter drug manufacturer ~~manufacturer's~~ permit is

PCB HCC 08-15

ORIGINAL

YEAR

1806 required for any person that engages in the manufacture or
 1807 repackaging of an over-the-counter drug.

1808 1. An over-the-counter drug manufacturer ~~permitter~~ may not
 1809 possess or purchase prescription drugs.

1810 2. A pharmacy is exempt from obtaining an over-the-counter
 1811 drug manufacturer's permit if it is operating in compliance with
 1812 pharmacy practice standards as defined in chapter 465 and the
 1813 rules adopted under that chapter.

1814 3. An over-the-counter drug manufacturer ~~permitter~~ must
 1815 comply with all appropriate state and federal good manufacturing
 1816 practices.

1817 (q) Device manufacturer permit. ~~(d)~~—A device manufacturer
 1818 ~~manufacturer's~~ permit is required for any person that engages in
 1819 the manufacture, repackaging, or assembly of medical devices for
 1820 human use in this state, except that a permit is not required if
 1821 the person is engaged only in manufacturing, repackaging, or
 1822 assembling a medical device pursuant to a practitioner's order
 1823 for a specific patient.

1824 1. A manufacturer or repackager of medical devices in this
 1825 state must comply with all appropriate state and federal good
 1826 manufacturing practices and quality system rules.

1827 2. The department shall adopt rules related to storage,
 1828 handling, and recordkeeping requirements for manufacturers of
 1829 medical devices for human use.

1830 (r) Cosmetic manufacturer permit. ~~(e)~~—A cosmetic
 1831 manufacturer ~~manufacturer's~~ permit is required for any person
 1832 that manufactures or repackages cosmetics in this state. A person
 1833 that only labels or changes the labeling of a cosmetic but does

PCB HCC 08-15

ORIGINAL

YEAR

1834 not open the container sealed by the manufacturer of the product
 1835 is exempt from obtaining a permit under this paragraph.

1836 Section 11. Section 499.012, Florida Statutes, is amended
 1837 and subsections (2)-(8) of section 499.01, Florida States, are
 1838 renumbered as subsections (1)-(7) of that section and amended to
 1839 read:

1840 499.012 Permit application ~~Wholesale distribution,~~
 1841 ~~definitions; permits; applications; general~~ requirements.--

1842 (1) ~~As used in this section, the term:~~

1843 ~~(2)~~(a) A permit issued pursuant to this part ~~ss. 499.001-~~
 1844 ~~499.081~~ may be issued only to a natural person who is at least 18
 1845 years of age or to an applicant that is not a natural person if
 1846 each person who, directly or indirectly, manages, controls, or
 1847 oversees the operation of that applicant is at least 18 years of
 1848 age.

1849 (b) An establishment that is a place of residence may not
 1850 receive a permit and may not operate under this part ~~ss. 499.001-~~
 1851 ~~499.081~~.

1852 (c) A person that applies for or renews a permit to
 1853 manufacture or distribute prescription ~~legend~~ drugs may not use a
 1854 name identical to the name used by any other establishment or
 1855 licensed person authorized to purchase prescription drugs in this
 1856 state, except that a restricted drug distributor permit issued to
 1857 a health care entity will be issued in the name in which the
 1858 institutional pharmacy permit is issued and a retail pharmacy
 1859 drug wholesale distributor ~~wholesaler~~ will be issued a permit in
 1860 the name of its retail pharmacy permit.

1861 (d) A permit for a prescription drug manufacturer,
 1862 prescription drug repackager, prescription drug wholesale

PCB HCC 08-15

ORIGINAL

YEAR

1863 | distributor ~~wholesaler~~, limited prescription drug veterinary
 1864 | wholesale distributor ~~wholesaler~~, or retail pharmacy wholesale
 1865 | distributor ~~wholesaler~~ may not be issued to the address of a
 1866 | health care entity or to a pharmacy licensed under chapter 465,
 1867 | except as provided in this paragraph. The department may issue a
 1868 | prescription drug manufacturer permit to an applicant at the same
 1869 | address as a licensed nuclear pharmacy, which is a health care
 1870 | entity, for the purpose of manufacturing prescription drugs used
 1871 | in positron emission tomography or other radiopharmaceuticals, as
 1872 | listed in a rule adopted by the department pursuant to this
 1873 | paragraph. The purpose of this exemption is to assure
 1874 | availability of state-of-the-art pharmaceuticals that would pose
 1875 | a significant danger to the public health if manufactured at a
 1876 | separate establishment address from the nuclear pharmacy from
 1877 | which the prescription drugs are dispensed. The department may
 1878 | also issue a retail pharmacy wholesale distributor ~~wholesaler~~
 1879 | permit to the address of a community pharmacy licensed under
 1880 | chapter 465 which does not meet the definition of a closed
 1881 | pharmacy in s. 499.003.

1882 | (e) A county or municipality may not issue an occupational
 1883 | license for any licensing period beginning on or after October 1,
 1884 | 2003, for any establishment that requires a permit pursuant to
 1885 | this part ~~ss. 499.001-499.081~~, unless the establishment exhibits
 1886 | a current permit issued by the department for the establishment.
 1887 | Upon presentation of the requisite permit issued by the
 1888 | department, an occupational license may be issued by the
 1889 | municipality or county in which application is made. The
 1890 | department shall furnish to local agencies responsible for
 1891 | issuing occupational licenses a current list of all

PCB HCC 08-15

ORIGINAL

YEAR

1892 establishments licensed pursuant to this part ~~ss. 499.001-~~
 1893 ~~499.081.~~

1894 (2)~~(3)~~ Notwithstanding subsection (6)~~(7)~~, a permitted
 1895 person in good standing may change the type of permit issued to
 1896 that person by completing a new application for the requested
 1897 permit, paying the amount of the difference in the permit fees if
 1898 the fee for the new permit is more than the fee for the original
 1899 permit, and meeting the applicable permitting conditions for the
 1900 new permit type. The new permit expires on the expiration date of
 1901 the original permit being changed; however, a new permit for a
 1902 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
 1903 state prescription drug wholesale distributor ~~wholesaler~~, or a
 1904 retail pharmacy drug wholesale distributor ~~wholesaler~~ shall
 1905 expire on the expiration date of the original permit or 1 year
 1906 after the date of issuance of the new permit, whichever is
 1907 earlier. A refund may not be issued if the fee for the new permit
 1908 is less than the fee that was paid for the original permit.

1909 (3)~~(4)~~ A written application for a permit or to renew a
 1910 permit must be filed with the department on forms furnished by
 1911 the department. The department shall establish, by rule, the form
 1912 and content of the application to obtain or renew a permit. The
 1913 applicant must submit to the department with the application a
 1914 statement that swears or affirms that the information is true and
 1915 correct.

1916 (4)~~(5)~~(a) Except for a permit for a prescription drug
 1917 wholesale distributor ~~wholesaler~~ or an out-of-state prescription
 1918 drug wholesale distributor ~~wholesaler~~, an application for a
 1919 permit must include:

PCB HCC 08-15

ORIGINAL

YEAR

1920 | 1. The name, full business address, and telephone number of
 1921 | the applicant;
 1922 | 2. All trade or business names used by the applicant;
 1923 | 3. The address, telephone numbers, and the names of contact
 1924 | persons for each facility used by the applicant for the storage,
 1925 | handling, and distribution of prescription drugs;
 1926 | 4. The type of ownership or operation, such as a
 1927 | partnership, corporation, or sole proprietorship; and
 1928 | 5. The names of the owner and the operator of the
 1929 | establishment, including:
 1930 | a. If an individual, the name of the individual;
 1931 | b. If a partnership, the name of each partner and the name
 1932 | of the partnership;
 1933 | c. If a corporation, the name and title of each corporate
 1934 | officer and director, the corporate names, and the name of the
 1935 | state of incorporation;
 1936 | d. If a sole proprietorship, the full name of the sole
 1937 | proprietor and the name of the business entity;
 1938 | e. If a limited liability company, the name of each member,
 1939 | the name of each manager, the name of the limited liability
 1940 | company, and the name of the state in which the limited liability
 1941 | company was organized; and
 1942 | f. Any other relevant information that the department
 1943 | requires.
 1944 | (b) Upon approval of the application by the department and
 1945 | payment of the required fee, the department shall issue a permit
 1946 | to the applicant, if the applicant meets the requirements of this
 1947 | part ~~ss. 499.001-499.081~~ and rules adopted under those sections.

PCB HCC 08-15

ORIGINAL

YEAR

1948 (c) Any change in information required under paragraph (a)
 1949 must be submitted to the department before the change occurs.

1950 (d) The department shall consider, at a minimum, the
 1951 following factors in reviewing the qualifications of persons to
 1952 be permitted under this part ~~ss. 499.001-499.081~~:

1953 1. The applicant's having been found guilty, regardless of
 1954 adjudication, in a court of this state or other jurisdiction, of
 1955 a violation of a law that directly relates to a drug, device, or
 1956 cosmetic. A plea of nolo contendere constitutes a finding of
 1957 guilt for purposes of this subparagraph.

1958 2. The applicant's having been disciplined by a regulatory
 1959 agency in any state for any offense that would constitute a
 1960 violation of this part ~~ss. 499.001-499.081~~.

1961 3. Any felony conviction of the applicant under a federal,
 1962 state, or local law;

1963 4. The applicant's past experience in manufacturing or
 1964 distributing drugs, devices, or cosmetics;

1965 5. The furnishing by the applicant of false or fraudulent
 1966 material in any application made in connection with manufacturing
 1967 or distributing drugs, devices, or cosmetics;

1968 6. Suspension or revocation by a federal, state, or local
 1969 government of any permit currently or previously held by the
 1970 applicant for the manufacture or distribution of any drugs,
 1971 devices, or cosmetics;

1972 7. Compliance with permitting requirements under any
 1973 previously granted permits;

1974 8. Compliance with requirements to maintain or make
 1975 available to the state permitting authority or to federal, state,

PCB HCC 08-15

ORIGINAL

YEAR

1976 | or local law enforcement officials those records required under
 1977 | this section; and

1978 | 9. Any other factors or qualifications the department
 1979 | considers relevant to and consistent with the public health and
 1980 | safety.

1981 | (5)~~(6)~~ Except for a permit ~~permits~~ for a prescription drug
 1982 | wholesale distributor ~~wholesalers~~ or an out-of-state prescription
 1983 | drug wholesale distributor ~~wholesalers~~:

1984 | (a) The department shall adopt rules for the biennial
 1985 | renewal of permits.

1986 | (b) The department shall renew a permit upon receipt of the
 1987 | renewal application and renewal fee if the applicant meets the
 1988 | requirements established under this part ~~ss. 499.001-499.081~~ and
 1989 | the rules adopted under those sections.

1990 | (c) A permit, unless sooner suspended or revoked,
 1991 | automatically expires 2 years after the last day of the
 1992 | anniversary month in which the permit was originally issued. A
 1993 | permit issued under this part ~~ss. 499.001-499.081~~ may be renewed
 1994 | by making application for renewal on forms furnished by the
 1995 | department and paying the appropriate fees. If a renewal
 1996 | application and fee are submitted and postmarked after the
 1997 | expiration date of the permit, the permit may be renewed only
 1998 | upon payment of a late renewal delinquent fee of \$100, plus the
 1999 | required renewal fee, not later than 60 days after the expiration
 2000 | date.

2001 | (d) Failure to renew a permit in accordance with this
 2002 | section precludes any future renewal of that permit. If a permit
 2003 | issued pursuant to this section has expired and cannot be
 2004 | renewed, before an establishment may engage in activities that

PCB HCC 08-15

ORIGINAL

YEAR

2005 require a permit under this part ~~ss. 499.001-499.081~~, the
 2006 establishment must submit an application for a new permit, pay
 2007 the applicable application fee, the initial permit fee, and all
 2008 applicable penalties, and be issued a new permit by the
 2009 department.

2010 (6)~~(7)~~ A permit issued by the department is
 2011 nontransferable. Each permit is valid only for the person or
 2012 governmental unit to which it is issued and is not subject to
 2013 sale, assignment, or other transfer, voluntarily or
 2014 involuntarily; nor is a permit valid for any establishment other
 2015 than the establishment for which it was originally issued.

2016 (a) A person permitted under this part ~~ss. 499.001-499.081~~
 2017 must notify the department before making a change of address. The
 2018 department shall set a change of location fee not to exceed \$100.

2019 (b)1. An application for a new permit is required when a
 2020 majority of the ownership or controlling interest of a permitted
 2021 establishment is transferred or assigned or when a lessee agrees
 2022 to undertake or provide services to the extent that legal
 2023 liability for operation of the establishment will rest with the
 2024 lessee. The application for the new permit must be made before
 2025 the date of the sale, transfer, assignment, or lease.

2026 2. A permittee that is authorized to distribute
 2027 prescription ~~legend~~ drugs may transfer such drugs to the new
 2028 owner or lessee under subparagraph 1. only after the new owner or
 2029 lessee has been approved for a permit to distribute prescription
 2030 ~~legend~~ drugs.

2031 (c) If an establishment permitted under this part ~~ss.~~
 2032 ~~499.001-499.081~~ closes, the owner must notify the department in
 2033 writing before the effective date of closure and must:

PCB HCC 08-15

ORIGINAL

YEAR

2034 1. Return the permit to the department;

2035 2. If the permittee is authorized to distribute

2036 prescription legend ~~legend~~ drugs, indicate the disposition of such

2037 drugs, including the name, address, and inventory, and provide

2038 the name and address of a person to contact regarding access to

2039 records that are required to be maintained under this part ss.

2040 ~~499.001-499.081~~. Transfer of ownership of prescription drugs may

2041 be made only to persons authorized to possess prescription legend

2042 drugs under this part ss. ~~499.001-499.081~~.

2043

2044 The department may revoke the permit of any person that fails to

2045 comply with the requirements of this subsection.

2046 ~~(7)-(8)~~ A permit must be posted in a conspicuous place on

2047 the licensed premises.

2048 ~~(8)-(3)~~ An application for a permit or to renew a permit for

2049 a prescription drug wholesale distributor ~~wholesaler~~ or an out-

2050 of-state prescription drug wholesale distributor ~~wholesaler~~

2051 submitted to the department must include:

2052 (a) The name, full business address, and telephone number

2053 of the applicant.

2054 (b) All trade or business names used by the applicant.

2055 (c) The address, telephone numbers, and the names of

2056 contact persons for each facility used by the applicant for the

2057 storage, handling, and distribution of prescription drugs.

2058 (d) The type of ownership or operation, such as a

2059 partnership, corporation, or sole proprietorship.

2060 (e) The names of the owner and the operator of the

2061 establishment, including:

2062 1. If an individual, the name of the individual.

PCB HCC 08-15

ORIGINAL

YEAR

2063 2. If a partnership, the name of each partner and the name
 2064 of the partnership.

2065 3. If a corporation:

2066 a. The name, address, and title of each corporate officer
 2067 and director.

2068 b. The name and address of the corporation, resident agent
 2069 of the corporation, the resident agent's address, and the
 2070 corporation's state of incorporation.

2071 c. The name and address of each shareholder of the
 2072 corporation that owns 5 percent or more of the outstanding stock
 2073 of the corporation.

2074 4. If a sole proprietorship, the full name of the sole
 2075 proprietor and the name of the business entity.

2076 5. If a limited liability company:

2077 a. The name and address of each member.

2078 b. The name and address of each manager.

2079 c. The name and address of the limited liability company,
 2080 the resident agent of the limited liability company, and the name
 2081 of the state in which the limited liability company was
 2082 organized.

2083 (f) If applicable, the name and address of each member of
 2084 the affiliated group of which the applicant is a member.

2085 (g)1. For an application for a new permit, the estimated
 2086 annual dollar volume of prescription drug sales of the applicant,
 2087 the estimated annual percentage of the applicant's total company
 2088 sales that are prescription drugs, the applicant's estimated
 2089 annual total dollar volume of purchases of prescription drugs,
 2090 and the applicant's estimated annual total dollar volume of
 2091 prescription drug purchases directly from manufacturers.

PCB HCC 08-15

ORIGINAL

YEAR

2092 2. For an application to renew a permit, the total dollar
 2093 volume of prescription drug sales in the previous year, the total
 2094 dollar volume of prescription drug sales made in the previous 6
 2095 months, the percentage of total company sales that were
 2096 prescription drugs in the previous year, the total dollar volume
 2097 of purchases of prescription drugs in the previous year, and the
 2098 total dollar volume of prescription drug purchases directly from
 2099 manufacturers in the previous year.

2100
 2101 Such portions of the information required pursuant to this
 2102 paragraph which are a trade secret, as defined in s. 812.081,
 2103 shall be maintained by the department as trade secret information
 2104 is required to be maintained under s. 499.051.

2105 (h) The tax year of the applicant.

2106 (i) A copy of the deed for the property on which
 2107 applicant's establishment is located, if the establishment is
 2108 owned by the applicant, or a copy of the applicant's lease for
 2109 the property on which applicant's establishment is located that
 2110 has an original term of not less than 1 calendar year, if the
 2111 establishment is not owned by the applicant.

2112 (j) A list of all licenses and permits issued to the
 2113 applicant by any other state which authorize the applicant to
 2114 purchase or possess prescription drugs.

2115 (k) The name of the manager of the establishment that is
 2116 applying for the permit or to renew the permit, the next four
 2117 highest ranking employees responsible for prescription drug
 2118 wholesale operations for the establishment, and the name of all
 2119 affiliated parties for the establishment, together with the

PCB HCC 08-15

ORIGINAL

YEAR

2120 personal information statement and fingerprints required pursuant
 2121 to subsection (9)~~(4)~~ for each of such persons.

2122 (l) The name of each of the applicant's designated
 2123 representatives as required by subsection (16)~~(11)~~, together with
 2124 the personal information statement and fingerprints required
 2125 pursuant to subsection (9)~~(4)~~ for each such person.

2126 (m) For an applicant that is a secondary wholesaler, each
 2127 of the following:

2128 1. A personal background information statement containing
 2129 the background information and fingerprints required pursuant to
 2130 subsection (9)~~(4)~~ for each person named in the applicant's
 2131 response to paragraphs (k) and (l) and for each affiliated party
 2132 of the applicant.

2133 2. If any of the five largest shareholders of the
 2134 corporation seeking the permit is a corporation, the name,
 2135 address, and title of each corporate officer and director of each
 2136 such corporation; the name and address of such corporation; the
 2137 name of such corporation's resident agent, such corporation's
 2138 resident agent's address, and such corporation's state of its
 2139 incorporation; and the name and address of each shareholder of
 2140 such corporation that owns 5 percent or more of the stock of such
 2141 corporation.

2142 3. The name and address of all financial institutions in
 2143 which the applicant has an account which is used to pay for the
 2144 operation of the establishment or to pay for drugs purchased for
 2145 the establishment, together with the names of all persons that
 2146 are authorized signatories on such accounts. The portions of the
 2147 information required pursuant to this subparagraph which are a
 2148 trade secret, as defined in s. 812.081, shall be maintained by

PCB HCC 08-15

ORIGINAL

YEAR

2149 | the department as trade secret information is required to be
 2150 | maintained under s. 499.051.

2151 | 4. The sources of all funds and the amounts of such funds
 2152 | used to purchase or finance purchases of prescription drugs or to
 2153 | finance the premises on which the establishment is to be located.

2154 | 5. If any of the funds identified in subparagraph 4. were
 2155 | borrowed, copies of all promissory notes or loans used to obtain
 2156 | such funds.

2157 | (n) Any other relevant information that the department
 2158 | requires, including, but not limited to, any information related
 2159 | to whether the applicant satisfies the definition of a primary
 2160 | wholesaler or a secondary wholesaler.

2161 | (9)~~(4)~~(a) Each person required by subsection (8)~~(3)~~ to
 2162 | provide a personal information statement and fingerprints shall
 2163 | provide the following information to the department on forms
 2164 | prescribed by the department:

2165 | 1. The person's places of residence for the past 7 years.

2166 | 2. The person's date and place of birth.

2167 | 3. The person's occupations, positions of employment, and
 2168 | offices held during the past 7 years.

2169 | 4. The principal business and address of any business,
 2170 | corporation, or other organization in which each such office of
 2171 | the person was held or in which each such occupation or position
 2172 | of employment was carried on.

2173 | 5. Whether the person has been, during the past 7 years,
 2174 | the subject of any proceeding for the revocation of any license
 2175 | and, if so, the nature of the proceeding and the disposition of
 2176 | the proceeding.

PCB HCC 08-15

ORIGINAL

YEAR

2177 | 6. Whether, during the past 7 years, the person has been
 2178 | enjoined, either temporarily or permanently, by a court of
 2179 | competent jurisdiction from violating any federal or state law
 2180 | regulating the possession, control, or distribution of
 2181 | prescription drugs, together with details concerning any such
 2182 | event.

2183 | 7. A description of any involvement by the person with any
 2184 | business, including any investments, other than the ownership of
 2185 | stock in a publicly traded company or mutual fund, during the
 2186 | past 7 years, which manufactured, administered, prescribed,
 2187 | distributed, or stored pharmaceutical products and any lawsuits
 2188 | in which such businesses were named as a party.

2189 | 8. A description of any felony criminal offense of which
 2190 | the person, as an adult, was found guilty, regardless of whether
 2191 | adjudication of guilt was withheld or whether the person pled
 2192 | guilty or nolo contendere. A criminal offense committed in
 2193 | another jurisdiction which would have been a felony in this state
 2194 | must be reported. If the person indicates that a criminal
 2195 | conviction is under appeal and submits a copy of the notice of
 2196 | appeal of that criminal offense, the applicant must, within 15
 2197 | days after the disposition of the appeal, submit to the
 2198 | department a copy of the final written order of disposition.

2199 | 9. A photograph of the person taken in the previous 30
 2200 | days.

2201 | 10. A set of fingerprints for the person on a form and
 2202 | under procedures specified by the department, together with
 2203 | payment of an amount equal to the costs incurred by the
 2204 | department for the criminal record check of the person.

PCB HCC 08-15

ORIGINAL

YEAR

2205 | 11. The name, address, occupation, and date and place of
 2206 | birth for each member of the person's immediate family who is 18
 2207 | years of age or older. As used in this subparagraph, the term
 2208 | "member of the person's immediate family" includes the person's
 2209 | spouse, children, parents, siblings, the spouses of the person's
 2210 | children, and the spouses of the person's siblings.

2211 | 12. Any other relevant information that the department
 2212 | requires.

2213 | (b) The information required pursuant to paragraph (a)
 2214 | shall be provided under oath.

2215 | (c) The department shall submit the fingerprints provided
 2216 | by a person for initial licensure to the Department of Law
 2217 | Enforcement for a statewide criminal record check and for
 2218 | forwarding to the Federal Bureau of Investigation for a national
 2219 | criminal record check of the person. The department shall submit
 2220 | the fingerprints provided by a person as a part of a renewal
 2221 | application to the Department of Law Enforcement for a statewide
 2222 | criminal record check, and for forwarding to the Federal Bureau
 2223 | of Investigation for a national criminal record check, for the
 2224 | initial renewal of a permit after January 1, 2004; for any
 2225 | subsequent renewal of a permit, the department shall submit the
 2226 | required information for a statewide and national criminal record
 2227 | check of the person. Any person who as a part of an initial
 2228 | permit application or initial permit renewal after January 1,
 2229 | 2004, submits to the department a set of fingerprints required
 2230 | for the criminal record check required in this paragraph shall
 2231 | not be required to provide a subsequent set of fingerprints for a
 2232 | criminal record check to the department, if the person has
 2233 | undergone a criminal record check as a condition of the issuance

PCB HCC 08-15

ORIGINAL

YEAR

2234 of an initial permit or the initial renewal of a permit of an
 2235 applicant after January 1, 2004.

2236 (10)~~(5)~~ The department may deny an application for a permit
 2237 or refuse to renew a permit for a prescription drug wholesale
 2238 distributor ~~wholesaler~~ or an out-of-state prescription drug
 2239 wholesale distributor ~~wholesaler~~ if:

2240 (a) The applicant has not met the requirements for the
 2241 permit.

2242 (b) The management, officers, or directors of the applicant
 2243 or any affiliated party are found by the department to be
 2244 incompetent or untrustworthy.

2245 (c) The applicant is so lacking in experience in managing a
 2246 wholesale distributor as to make the issuance of the proposed
 2247 permit hazardous to the public health.

2248 (d) The applicant is so lacking in experience in managing a
 2249 wholesale distributor as to jeopardize the reasonable promise of
 2250 successful operation of the wholesale distributor.

2251 (e) The applicant is lacking in experience in the
 2252 distribution of prescription drugs.

2253 (f) The applicant's past experience in manufacturing or
 2254 distributing prescription drugs indicates that the applicant
 2255 poses a public health risk.

2256 (g) The applicant is affiliated directly or indirectly
 2257 through ownership, control, or other business relations, with any
 2258 person or persons whose business operations are or have been
 2259 detrimental to the public health.

2260 (h) The applicant, or any affiliated party, has been found
 2261 guilty of or has pleaded guilty or nolo contendere to any felony
 2262 or crime punishable by imprisonment for 1 year or more under the

PCB HCC 08-15

ORIGINAL

YEAR

2263 laws of the United States, any state, or any other country,
 2264 regardless of whether adjudication of guilt was withheld.

2265 (i) The applicant or any affiliated party has been charged
 2266 with a felony in a state or federal court and the disposition of
 2267 that charge is pending during the application review or renewal
 2268 review period.

2269 (j) The applicant has furnished false or fraudulent
 2270 information or material in any application made in this state or
 2271 any other state in connection with obtaining a permit or license
 2272 to manufacture or distribute drugs, devices, or cosmetics.

2273 (k) That a federal, state, or local government permit
 2274 currently or previously held by the applicant, or any affiliated
 2275 party, for the manufacture or distribution of any drugs, devices,
 2276 or cosmetics has been disciplined, suspended, or revoked and has
 2277 not been reinstated.

2278 (l) The applicant does not possess the financial or
 2279 physical resources to operate in compliance with the permit being
 2280 sought, this chapter, and the rules adopted under this chapter.

2281 (m) The applicant or any affiliated party receives,
 2282 directly or indirectly, financial support and assistance from a
 2283 person who was an affiliated party of a permittee whose permit
 2284 was subject to discipline or was suspended or revoked, other than
 2285 through the ownership of stock in a publicly traded company or a
 2286 mutual fund.

2287 (n) The applicant or any affiliated party receives,
 2288 directly or indirectly, financial support and assistance from a
 2289 person who has been found guilty of any violation of this part
 2290 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,
 2291 any rules adopted under any of those sections or chapters, any

PCB HCC 08-15

ORIGINAL

YEAR

2292 federal or state drug law, or any felony where the underlying
 2293 facts related to drugs, regardless of whether the person has been
 2294 pardoned, had her or his civil rights restored, or had
 2295 adjudication withheld, other than through the ownership of stock
 2296 in a publicly traded company or a mutual fund.

2297 (o) The applicant for renewal of a permit under paragraph
 2298 (1) (d) ~~(2) (a)~~ or paragraph (1) (e) ~~(2) (e)~~ of s. 499.01 has not
 2299 actively engaged in the wholesale distribution of prescription
 2300 drugs, as demonstrated by the regular and systematic distribution
 2301 of prescription drugs throughout the year as evidenced by not
 2302 fewer than 12 wholesale distributions in the previous year and
 2303 not fewer than three wholesale distributions in the previous 6
 2304 months.

2305 (p) Information obtained in response to paragraph
 2306 (1) (d) ~~(2) (a)~~ or paragraph (1) (e) ~~(2) (e)~~ of s. 499.01 demonstrates
 2307 it would not be in the best interest of the public health,
 2308 safety, and welfare to issue a permit.

2309 (q) The applicant does not possess the financial standing
 2310 and business experience for the successful operation of the
 2311 applicant.

2312 (r) The applicant or any affiliated party has failed to
 2313 comply with the requirements for manufacturing or distributing
 2314 prescription drugs under this part ~~ss. 499.001-499.081~~, similar
 2315 federal laws, similar laws in other states, or the rules adopted
 2316 under such laws.

2317 ~~(11) (6)~~ Upon approval of the application by the department
 2318 and payment of the required fee, the department shall issue or
 2319 renew a prescription drug wholesaler or an out-of-state
 2320 prescription drug wholesaler permit to the applicant.

PCB HCC 08-15

ORIGINAL

YEAR

2321 | (12)-(7) For a permit ~~permits~~ for a prescription drug
 2322 | wholesale distributor ~~wholesalers~~ or an out-of-state prescription
 2323 | drug wholesale distributor ~~wholesalers~~:

2324 | (a) The department shall adopt rules for the annual renewal
 2325 | of permits. At least 90 days before the expiration of a permit,
 2326 | the department shall forward a permit renewal notification and
 2327 | renewal application to the prescription drug wholesale
 2328 | distributor ~~wholesaler~~ or out-of-state prescription drug
 2329 | wholesale distributor ~~wholesaler~~ at the mailing address of the
 2330 | permitted establishment on file with the department. The permit
 2331 | renewal notification must state conspicuously the date on which
 2332 | the permit for the establishment will expire and that the
 2333 | establishment may not operate unless the permit for the
 2334 | establishment is renewed timely.

2335 | (b) A permit, unless sooner suspended or revoked,
 2336 | automatically expires 1 year after the last day of the
 2337 | anniversary month in which the permit was originally issued. A
 2338 | permit may be renewed by making application for renewal on forms
 2339 | furnished by the department and paying the appropriate fees. If a
 2340 | renewal application and fee are submitted and postmarked after 45
 2341 | days prior to the expiration date of the permit, the permit may
 2342 | be renewed only upon payment of a late renewal fee of \$100, plus
 2343 | the required renewal fee. A permittee that has submitted a
 2344 | renewal application in accordance with this paragraph may
 2345 | continue to operate under its permit, unless the permit is
 2346 | suspended or revoked, until final disposition of the renewal
 2347 | application.

2348 | (c) Failure to renew a permit in accordance with this
 2349 | section precludes any future renewal of that permit. If a permit

PCB HCC 08-15

ORIGINAL

YEAR

2350 issued pursuant to this section has expired and cannot be
 2351 renewed, before an establishment may engage in activities that
 2352 require a permit under this part ~~ss. 499.001-499.081~~, the
 2353 establishment must submit an application for a new permit; pay
 2354 the applicable application fee, initial permit fee, and all
 2355 applicable penalties; and be issued a new permit by the
 2356 department.

2357 ~~(13)-(8)~~ A person that engages in wholesale distribution of
 2358 prescription drugs in this state must have a wholesale
 2359 distributor's permit issued by the department, except as noted in
 2360 this section. Each establishment must be separately permitted
 2361 except as noted in this subsection.

2362 (a) A separate establishment permit is not required when a
 2363 permitted prescription drug wholesale distributor ~~wholesaler~~
 2364 consigns a prescription drug to a pharmacy that is permitted
 2365 under chapter 465 and located in this state, provided that:

2366 1. The consignor wholesale distributor ~~wholesaler~~ notifies
 2367 the department in writing of the contract to consign prescription
 2368 drugs to a pharmacy along with the identity and location of each
 2369 consignee pharmacy;

2370 2. The pharmacy maintains its permit under chapter 465;

2371 3. The consignor wholesale distributor ~~wholesaler~~, which
 2372 has no legal authority to dispense prescription drugs, complies
 2373 with all wholesale distribution requirements of s. 499.0121 and
 2374 499.012111 with respect to the consigned drugs and maintains
 2375 records documenting the transfer of title or other completion of
 2376 the wholesale distribution of the consigned prescription drugs;

2377 4. The distribution of the prescription drug is otherwise
 2378 lawful under this chapter and other applicable law;

PCB HCC 08-15

ORIGINAL

YEAR

2379 | 5. Open packages containing prescription drugs within a
 2380 | pharmacy are the responsibility of the pharmacy, regardless of
 2381 | how the drugs are titled; and

2382 | 6. The pharmacy dispenses the consigned prescription drug
 2383 | in accordance with the limitations of its permit under chapter
 2384 | 465 or returns the consigned prescription drug to the consignor
 2385 | wholesale distributor ~~wholesaler~~. In addition, a person who holds
 2386 | title to prescription drugs may transfer the drugs to a person
 2387 | permitted or licensed to handle the reverse distribution or
 2388 | destruction of drugs. Any other distribution by and means of the
 2389 | consigned prescription drug by any person, not limited to the
 2390 | consignor wholesaler or consignee pharmacy, to any other person
 2391 | is prohibited.

2392 | (b) A wholesale distributor's permit is not required for
 2393 | the one-time transfer of title of a pharmacy's lawfully acquired
 2394 | prescription drug inventory by a pharmacy with a valid permit
 2395 | issued under chapter 465 to a consignor prescription drug
 2396 | wholesale distributor ~~wholesaler~~, permitted under this chapter,
 2397 | in accordance with a written consignment agreement between the
 2398 | pharmacy and that wholesale distributor ~~wholesaler~~ if+ the
 2399 | permitted pharmacy and the permitted prescription drug wholesale
 2400 | distributor ~~wholesaler~~ comply with all of the provisions of
 2401 | paragraph (a) and the prescription drugs continue to be within
 2402 | the permitted pharmacy's inventory for dispensing in accordance
 2403 | with the limitations of the pharmacy permit under chapter 465. A
 2404 | consignor drug wholesale distributor ~~wholesaler~~ may not use the
 2405 | pharmacy as a wholesale distributor through which it distributes
 2406 | the prescription ~~legend~~ drugs to other pharmacies. Nothing in
 2407 | this section is intended to prevent a wholesale ~~drug~~ distributor

PCB HCC 08-15

ORIGINAL

YEAR

2408 | from obtaining this inventory in the event of nonpayment by the
2409 | pharmacy.

2410 | (c) The department shall require information from each
2411 | wholesale distributor as part of the permit and renewal of such
2412 | permit, as required under ~~s. 499.01~~ or this section.

2413 | (14)~~(9)~~ Personnel employed in wholesale distribution must
2414 | have appropriate education and experience to enable them to
2415 | perform their duties in compliance with state permitting
2416 | requirements.

2417 | (15)~~(10)~~ The name of a permittee or establishment on a
2418 | prescription drug wholesale distributor ~~wholesaler~~ permit or an
2419 | out-of-state prescription drug wholesale distributor ~~wholesaler~~
2420 | permit may not include any indicia of attainment of any
2421 | educational degree, any indicia that the permittee or
2422 | establishment possesses a professional license, or any name or
2423 | abbreviation that the department determines is likely to cause
2424 | confusion or mistake or that the department determines is
2425 | deceptive, including that of any other entity authorized to
2426 | purchase prescription drugs.

2427 | (16)~~(11)~~(a) Each establishment that is issued an initial or
2428 | renewal permit as a prescription drug wholesale distributor
2429 | ~~wholesaler~~ or an out-of-state prescription drug wholesale
2430 | distributor ~~wholesaler~~ must designate in writing to the
2431 | department at least one natural person to serve as the designated
2432 | representative of the wholesale distributor ~~wholesaler~~. Such
2433 | person must have an active certification as a designated
2434 | representative from the department.

2435 | (b) To be certified as a designated representative, a
2436 | natural person must:

PCB HCC 08-15

ORIGINAL

YEAR

- 2437 | 1. Submit an application on a form furnished by the
 2438 | department and pay the appropriate fees;
 2439 | 2. Be at least 18 years of age;
 2440 | 3. Have not less than 2 years of verifiable full-time work
 2441 | experience in a pharmacy licensed in this state or another state,
 2442 | where the person's responsibilities included, but were not
 2443 | limited to, recordkeeping for prescription drugs, or have not
 2444 | less than 2 years of verifiable full-time managerial experience
 2445 | with a prescription drug wholesale distributor ~~wholesaler~~
 2446 | licensed in this state or in another state;
 2447 | 4. Receive a passing score of at least 75 percent on an
 2448 | examination given by the department regarding federal laws
 2449 | governing distribution of prescription drugs and this part ss.
 2450 | ~~499.001-499.081~~ and the rules adopted by the department governing
 2451 | the wholesale distribution of prescription drugs. This
 2452 | requirement shall be effective 1 year after the results of the
 2453 | initial examination are mailed to the persons that took the
 2454 | examination. The department shall offer such examinations at
 2455 | least four times each calendar year; and
 2456 | 5. Provide the department with a personal information
 2457 | statement and fingerprints pursuant to subsection (9)~~(4)~~.
 2458 | (c) The department may deny an application for
 2459 | certification as a designated representative or may suspend or
 2460 | revoke a certification of a designated representative pursuant to
 2461 | s. 499.067.
 2462 | (d) A designated representative:
 2463 | 1. Must be actively involved in and aware of the actual
 2464 | daily operation of the wholesale distributor.

PCB HCC 08-15

ORIGINAL

YEAR

2465 | 2. Must be employed full time in a managerial position by
2466 | the wholesale distributor.

2467 | 3. Must be physically present at the establishment during
2468 | normal business hours, except for time periods when absent due to
2469 | illness, family illness or death, scheduled vacation, or other
2470 | authorized absence.

2471 | 4. May serve as a designated representative for only one
2472 | wholesale distributor at any one time.

2473 | (e) A wholesale distributor must notify the department when
2474 | a designated representative leaves the employ of the wholesale
2475 | distributor. Such notice must be provided to the department
2476 | within 10 business days after the last day of designated
2477 | representative's employment with the wholesale distributor.

2478 | (f) A wholesale distributor may not operate under a
2479 | prescription drug wholesale distributor ~~wholesaler~~ permit or an
2480 | out-of-state prescription drug wholesale distributor ~~wholesaler~~
2481 | permit for more than 10 business days after the designated
2482 | representative leaves the employ of the wholesale distributor,
2483 | unless the wholesale distributor employs another designated
2484 | representative and notifies the department within 10 business
2485 | days of the identity of the new designated representative.

2486 | Section 12. Section 499.01201, Florida Statutes, is amended
2487 | to read:

2488 | 499.01201 Agency for Health Care Administration review and
2489 | use of statute and rule violation or compliance data.--
2490 | Notwithstanding any other provisions of law to the contrary, the
2491 | Agency for Health Care Administration may not:

2492 | (1) Review or use any violation or alleged violation of ss.
2493 | 499.0121(6) or 499.012111, or any rules adopted under those

PCB HCC 08-15

ORIGINAL

YEAR

2494 sections ~~that section~~, as a ground for denying or withholding any
 2495 payment of a Medicaid reimbursement to a pharmacy licensed under
 2496 chapter 465; or

2497 (2) Review or use compliance with ss. 499.0121(6) or
 2498 499.012111, or any rules adopted under those sections ~~that~~
 2499 ~~section~~, as the subject of any audit of Medicaid-related records
 2500 held by a pharmacy licensed under chapter 465.

2501 Section 13. Section 499.0121, Florida Statutes, is amended
 2502 and subsection (4) of section 499.013, Florida Statutes, is
 2503 renumbered as paragraph (6)(d) of that section and amended to
 2504 read:

2505 499.0121 Storage and handling of prescription drugs;
 2506 recordkeeping.--The department shall adopt rules to implement
 2507 this section as necessary to protect the public health, safety,
 2508 and welfare. Such rules shall include, but not be limited to,
 2509 requirements for the storage and handling of prescription drugs
 2510 and for the establishment and maintenance of prescription drug
 2511 distribution records.

2512 (1) ESTABLISHMENTS.--An establishment at which prescription
 2513 drugs are stored, warehoused, handled, held, offered, marketed,
 2514 or displayed must:

2515 (a) Be of suitable size and construction to facilitate
 2516 cleaning, maintenance, and proper operations;

2517 (b) Have storage areas designed to provide adequate
 2518 lighting, ventilation, temperature, sanitation, humidity, space,
 2519 equipment, and security conditions;

2520 (c) Have a quarantine area for storage of prescription
 2521 drugs that are outdated, damaged, deteriorated, misbranded, or

PCB HCC 08-15

ORIGINAL

YEAR

2522 adulterated, or that are in immediate or sealed, secondary
 2523 containers that have been opened;
 2524 (d) Be maintained in a clean and orderly condition; and
 2525 (e) Be free from infestation by insects, rodents, birds, or
 2526 vermin of any kind.
 2527 (2) SECURITY.--
 2528 (a) An establishment that is used for wholesale drug
 2529 distribution must be secure from unauthorized entry.
 2530 1. Access from outside the premises must be kept to a
 2531 minimum and be well-controlled.
 2532 2. The outside perimeter of the premises must be well-
 2533 lighted.
 2534 3. Entry into areas where prescription drugs are held must
 2535 be limited to authorized personnel.
 2536 (b) An establishment that is used for wholesale drug
 2537 distribution must be equipped with:
 2538 1. An alarm system to detect entry after hours; however,
 2539 the department may exempt by rule establishments that only hold a
 2540 permit as prescription drug wholesale distributor ~~wholesaler-~~
 2541 brokers and establishments that only handle medical oxygen; and
 2542 2. A security system that will provide suitable protection
 2543 against theft and diversion. When appropriate, the security
 2544 system must provide protection against theft or diversion that is
 2545 facilitated or hidden by tampering with computers or electronic
 2546 records.
 2547 (c) Any vehicle that contains prescription drugs must be
 2548 secure from unauthorized access to the prescription drugs in the
 2549 vehicle.

PCB HCC 08-15

ORIGINAL

YEAR

2550 (3) STORAGE.--All prescription drugs shall be stored at
 2551 appropriate temperatures and under appropriate conditions in
 2552 accordance with requirements, if any, in the labeling of such
 2553 drugs, or with requirements in the official compendium.

2554 (a) If no storage requirements are established for a
 2555 prescription drug, the drug may be held at "controlled" room
 2556 temperature, as defined in the official compendium, to help
 2557 ensure that its identity, strength, quality, and purity are not
 2558 adversely affected.

2559 (b) Appropriate manual, electromechanical, or electronic
 2560 temperature and humidity recording equipment, devices, or logs
 2561 must be used to document proper storage of prescription drugs.

2562 (c) The recordkeeping requirements in subsection (6) must
 2563 be followed for all stored prescription drugs.

2564 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2565 (a) Upon receipt, each outside shipping container must be
 2566 visually examined for identity and to prevent the acceptance of
 2567 contaminated prescription drugs that are otherwise unfit for
 2568 distribution. This examination must be adequate to reveal
 2569 container damage that would suggest possible contamination or
 2570 other damage to the contents.

2571 (b) Each outgoing shipment must be carefully inspected for
 2572 identity of the prescription drug products and to ensure that
 2573 there is no delivery of prescription drugs that have expired or
 2574 been damaged in storage or held under improper conditions.

2575 (c) The recordkeeping requirements in subsection (6) must
 2576 be followed for all incoming and outgoing prescription drugs.

2577 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must
 2578 review records required under this section for the acquisition of

PCB HCC 08-15

ORIGINAL

YEAR

2579 prescription drugs for accuracy and completeness, considering the
 2580 total facts and circumstances surrounding the transactions and
 2581 the wholesale distributors involved. This includes authenticating
 2582 each transaction listed on a pedigree paper, as defined in s.
 2583 499.003(37) ~~499.001(31)~~.

2584 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

2585 (a)1. Prescription drugs that are outdated, damaged,
 2586 deteriorated, misbranded, or adulterated must be quarantined and
 2587 physically separated from other prescription drugs until they are
 2588 destroyed or returned to their supplier. A quarantine section
 2589 must be separate and apart from other sections where prescription
 2590 drugs are stored so that prescription drugs in this section are
 2591 not confused with usable prescription drugs.

2592 2. Prescription drugs must be examined at least every 12
 2593 months, and drugs for which the expiration date has passed must
 2594 be removed and quarantined.

2595 (b) Any prescription drugs of which the immediate or sealed
 2596 outer containers or sealed secondary containers have been opened
 2597 or used must be identified as such and must be quarantined and
 2598 physically separated from other prescription drugs until they are
 2599 either destroyed or returned to the supplier.

2600 (c) If the conditions under which a prescription drug has
 2601 been returned cast doubt on the drug's safety, identity,
 2602 strength, quality, or purity, the drug must be destroyed or
 2603 returned to the supplier, unless examination, testing, or other
 2604 investigation proves that the drug meets appropriate standards of
 2605 safety, identity, strength, quality, and purity. In determining
 2606 whether the conditions under which a drug has been returned cast
 2607 doubt on the drug's safety, identity, strength, quality, or

PCB HCC 08-15

ORIGINAL

YEAR

2608 | purity, the wholesale ~~drug~~ distributor must consider, among other
 2609 | things, the conditions under which the drug has been held,
 2610 | stored, or shipped before or during its return and the conditions
 2611 | of the drug and its container, carton, or labeling, as a result
 2612 | of storage or shipping.

2613 | (d) The recordkeeping requirements in subsection (6) must
 2614 | be followed for all outdated, damaged, deteriorated, misbranded,
 2615 | or adulterated prescription drugs.

2616 | (6) RECORDKEEPING.--The department shall adopt rules that
 2617 | require keeping such records of prescription drugs as are
 2618 | necessary for the protection of the public health.

2619 | (a) Wholesale ~~drug~~ distributors must establish and maintain
 2620 | inventories and records of all transactions regarding the receipt
 2621 | and distribution or other disposition of prescription drugs.
 2622 | These records must provide a complete audit trail from receipt to
 2623 | sale or other disposition, be readily retrievable for inspection,
 2624 | and include, at a minimum, the following information:

2625 | 1. The source of the drugs, including the name and
 2626 | principal address of the seller or transferor, and the address of
 2627 | the location from which the drugs were shipped;

2628 | 2. The name, principal address, and state license permit or
 2629 | registration number of the person authorized to purchase
 2630 | prescription drugs;

2631 | 3. The name, strength, dosage form, and quantity of the
 2632 | drugs received and distributed or disposed of;

2633 | 4. The dates of receipt and distribution or other
 2634 | disposition of the drugs; and

2635 | 5. Any financial documentation supporting the transaction.

PCB HCC 08-15

ORIGINAL

YEAR

2636 (b) Inventories and records must be made available for
 2637 inspection and photocopying by authorized federal, state, or
 2638 local officials for a period of 2 years following disposition of
 2639 the drugs or 3 years after the creation of the records, whichever
 2640 period is longer.

2641 (c) Records described in this section that are kept at the
 2642 inspection site or that can be immediately retrieved by computer
 2643 or other electronic means must be readily available for
 2644 authorized inspection during the retention period. Records that
 2645 are kept at a central location outside of this state and that are
 2646 not electronically retrievable must be made available for
 2647 inspection within 2 working days after a request by an authorized
 2648 official of a federal, state, or local law enforcement agency.
 2649 Records that are maintained at a central location within this
 2650 state must be maintained at an establishment that is permitted
 2651 pursuant to this part ~~ss. 499.001-499.081~~ and must be readily
 2652 available.

2653 (d) Each manufacturer or repackager of medical devices,
 2654 over-the-counter drugs, or cosmetics must maintain records that
 2655 include the name and principal address of the seller or
 2656 transferor of the product, the address of the location from which
 2657 the product was shipped, the date of the transaction, the name
 2658 and quantity of the product involved, and the name and principal
 2659 address of the person who purchased the product.

2660 (e) A wholesale distributor must maintain pedigree papers
 2661 separate and distinct from other records required under this
 2662 chapter.

2663 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~
 2664 ~~the wholesale distribution of a prescription drug and who is not~~

PCB HCC 08-15

ORIGINAL

YEAR

2665 | ~~the manufacturer of that drug must, before each wholesale~~
 2666 | ~~distribution of such drug, provide to the person who receives the~~
 2667 | ~~drug a pedigree paper as defined in s. 499.003(31).~~
 2668 | ~~2. A repackager must comply with this paragraph.~~
 2669 | ~~3. The pedigree paper requirements in this paragraph do not~~
 2670 | ~~apply to compressed medical gases or veterinary legend drugs.~~
 2671 | ~~4. Each wholesale distributor of prescription drugs must~~
 2672 | ~~maintain separate and distinct from other required records all~~
 2673 | ~~statements that are required under subparagraph 1.~~
 2674 | ~~5. Subparagraph 1. is satisfied when a wholesale~~
 2675 | ~~distributor takes title to, but not possession of, a prescription~~
 2676 | ~~drug and the prescription drug's manufacturer ships the~~
 2677 | ~~prescription drug directly to a person authorized by law to~~
 2678 | ~~purchase prescription drugs for the purpose of administering or~~
 2679 | ~~dispensing the drug, as defined in s. 465.003, or a member of an~~
 2680 | ~~affiliated group, as described in paragraph (f), with the~~
 2681 | ~~exception of a repackager.~~
 2682 | ~~a. The wholesale distributor must deliver to the recipient~~
 2683 | ~~of the prescription drug, within 14 days after the shipment~~
 2684 | ~~notification from the manufacturer, an invoice and the following~~
 2685 | ~~sworn statement: "This wholesale distributor purchased the~~
 2686 | ~~specific unit of the prescription drug listed on the invoice~~
 2687 | ~~directly from the manufacturer, and the specific unit of~~
 2688 | ~~prescription drug was shipped by the manufacturer directly to a~~
 2689 | ~~person authorized by law to administer or dispense the legend~~
 2690 | ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~
 2691 | ~~an affiliated group, as described in s. 499.0121(6) (f), Florida~~
 2692 | ~~Statutes, with the exception of a repackager." The invoice must~~

PCB HCC 08-15

ORIGINAL

YEAR

2693 ~~contain a unique cross-reference to the shipping document sent by~~
 2694 ~~the manufacturer to the recipient of the prescription drug.~~

2695 ~~b. The manufacturer of the prescription drug shipped~~
 2696 ~~directly to the recipient under this section must provide and the~~
 2697 ~~recipient of the prescription drug must acquire, within 14 days~~
 2698 ~~after receipt of the prescription drug, a shipping document from~~
 2699 ~~the manufacturer that contains, at a minimum:~~

2700 ~~(I) The name and address of the manufacturer, including the~~
 2701 ~~point of origin of the shipment, and the names and addresses of~~
 2702 ~~the wholesaler and the purchaser.~~

2703 ~~(II) The name of the prescription drug as it appears on the~~
 2704 ~~label.~~

2705 ~~(III) The quantity, dosage form, and strength of the~~
 2706 ~~prescription drug.~~

2707 ~~(IV) The date of the shipment from the manufacturer.~~

2708 ~~e. The wholesale distributor must also maintain and make~~
 2709 ~~available to the department, upon request, the lot number of such~~
 2710 ~~drug if not contained in the shipping document acquired by the~~
 2711 ~~recipient.~~

2712 ~~6. Failure of the manufacturer to provide, the recipient to~~
 2713 ~~acquire, or the wholesale distributor to deliver, the~~
 2714 ~~documentation required under subparagraph 5. shall constitute~~
 2715 ~~failure to acquire or deliver a pedigree paper under s. 499.0051.~~
 2716 ~~Forgery by the manufacturer, the recipient, or the wholesale~~
 2717 ~~distributor of the documentation required to be acquired or~~
 2718 ~~delivered under subparagraph 5. shall constitute forgery of a~~
 2719 ~~pedigree paper under s. 499.0051. 7. The department may, by~~
 2720 ~~rule, specify alternatives to compliance with subparagraph 1. for~~
 2721 ~~a prescription drug in the inventory of a permitted prescription~~

PCB HCC 08-15

ORIGINAL

YEAR

2722 ~~drug wholesaler as of June 30, 2006, and the return of a~~
 2723 ~~prescription drug purchased prior to July 1, 2006. The department~~
 2724 ~~may specify time limits for such alternatives.~~

2725 (7)~~(e)~~ Each wholesale distributor, except for a
 2726 manufacturer, shall annually provide the department with a
 2727 written list of all wholesale distributors and manufacturers from
 2728 whom the wholesale distributor purchases prescription drugs. A
 2729 wholesale distributor, except a manufacturer, shall notify the
 2730 department not later than 10 days after any change to either
 2731 list. Such portions of the information required pursuant to this
 2732 paragraph which are a trade secret, as defined in s. 812.081,
 2733 shall be maintained by the department as trade secret information
 2734 is required to be maintained under s. 499.051.

2735 ~~(f)1. This paragraph applies only to an affiliated group,~~
 2736 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~
 2737 ~~amended, which is composed of chain drug entities, including at~~
 2738 ~~least 50 retail pharmacies, warehouses, or repackagers, which are~~
 2739 ~~members of the same affiliated group, if the affiliated group:~~

2740 ~~a. Discloses to the department the names of all its~~
 2741 ~~members; and~~

2742 ~~b. Agrees in writing to provide records on prescription~~
 2743 ~~drug purchases by members of the affiliated group not later than~~
 2744 ~~48 hours after the department requests such records, regardless~~
 2745 ~~of the location where the records are stored.~~

2746 ~~2. Each warehouse within the affiliated group must comply~~
 2747 ~~with all applicable federal and state drug wholesale permit~~
 2748 ~~requirements and must purchase, receive, hold, and distribute~~
 2749 ~~prescription drugs only to a retail pharmacy or warehouse within~~
 2750 ~~the affiliated group. Such a warehouse is exempt from providing a~~

PCB HCC 08-15

ORIGINAL

YEAR

2751 ~~pedigree paper in accordance with paragraph (d) to its affiliated~~
 2752 ~~group member warehouse or retail pharmacy, provided that:~~

2753 ~~a. Any affiliated group member that purchases or receives a~~
 2754 ~~prescription drug from outside the affiliated group must receive~~
 2755 ~~a pedigree paper if the prescription drug is distributed in or~~
 2756 ~~into this state and a pedigree paper is required under this~~
 2757 ~~section and must authenticate the documentation as required in~~
 2758 ~~subsection (4), regardless of whether the affiliated group member~~
 2759 ~~is directly subject to regulation under this chapter; and~~

2760 ~~b. The affiliated group makes available to the department~~
 2761 ~~on request all records related to the purchase or acquisition of~~
 2762 ~~prescription drugs by members of the affiliated group, regardless~~
 2763 ~~of the location where the records are stored, if the prescription~~
 2764 ~~drugs were distributed in or into this state.~~

2765 ~~3. If a repackager repackages prescription drugs solely for~~
 2766 ~~distribution to its affiliated group members for the exclusive~~
 2767 ~~distribution to and among retail pharmacies that are members of~~
 2768 ~~the affiliated group to which the repackager is a member:~~

2769 ~~a. The repackager must:~~

2770 ~~(I) In lieu of the written statement required by paragraph~~
 2771 ~~(d), for all repackaged prescription drugs distributed in or into~~
 2772 ~~this state, state in writing under oath with each distribution of~~
 2773 ~~a repackaged prescription drug to an affiliated group member~~
 2774 ~~warehouse or repackager: "All repackaged prescription drugs are~~
 2775 ~~purchased by the affiliated group directly from the manufacturer~~
 2776 ~~or from a prescription drug wholesaler that purchased the~~
 2777 ~~prescription drugs directly from the manufacturer.";~~

2778 ~~(II) Purchase all prescription drugs it repackages:~~

2779 ~~(A) Directly from the manufacturer; or~~

PCB HCC 08-15

ORIGINAL

YEAR

2780 ~~(B) From a prescription drug wholesaler that purchased the~~
 2781 ~~prescription drugs directly from the manufacturer; and~~

2782 ~~(III) Maintain records in accordance with this section to~~
 2783 ~~document that it purchased the prescription drugs directly from~~
 2784 ~~the manufacturer or that its prescription drug wholesale supplier~~
 2785 ~~purchased the prescription drugs directly from the manufacturer.~~

2786 ~~b. All members of the affiliated group must provide to~~
 2787 ~~agents of the department on request records of purchases by all~~
 2788 ~~members of the affiliated group of prescription drugs that have~~
 2789 ~~been repackaged, regardless of the location where the records are~~
 2790 ~~stored or where the repackager is located.~~

2791 (8)~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale drug
 2792 distributors must establish, maintain, and adhere to written
 2793 policies and procedures, which must be followed for the receipt,
 2794 security, storage, inventory, and distribution of prescription
 2795 drugs, including policies and procedures for identifying,
 2796 recording, and reporting losses or thefts, and for correcting all
 2797 errors and inaccuracies in inventories. Wholesale drug
 2798 distributors must include in their written policies and
 2799 procedures:

2800 (a) A procedure whereby the oldest approved stock of a
 2801 prescription drug product is distributed first. The procedure may
 2802 permit deviation from this requirement, if the deviation is
 2803 temporary and appropriate.

2804 (b) A procedure to be followed for handling recalls and
 2805 withdrawals of prescription drugs. Such procedure must be
 2806 adequate to deal with recalls and withdrawals due to:

PCB HCC 08-15

ORIGINAL

YEAR

2807 1. Any action initiated at the request of the Food and Drug
 2808 Administration or any other federal, state, or local law
 2809 enforcement or other government agency, including the department.

2810 2. Any voluntary action by the manufacturer or repackager
 2811 to remove defective or potentially defective drugs from the
 2812 market; or

2813 3. Any action undertaken to promote public health and
 2814 safety by replacing existing merchandise with an improved product
 2815 or new package design.

2816 (c) A procedure to ensure that wholesale ~~drug~~ distributors
 2817 prepare for, protect against, and handle any crisis that affects
 2818 security or operation of any facility if a strike, fire, flood,
 2819 or other natural disaster, or a local, state, or national
 2820 emergency, occurs.

2821 (d) A procedure to ensure that any outdated prescription
 2822 drugs are segregated from other drugs and either returned to the
 2823 manufacturer or repackager or destroyed. This procedure must
 2824 provide for written documentation of the disposition of outdated
 2825 prescription drugs. This documentation must be maintained for 2
 2826 years after disposition of the outdated drugs.

2827 (9)~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors
 2828 must establish and maintain lists of officers, directors,
 2829 managers, designated representatives, and other persons in charge
 2830 of wholesale drug distribution, storage, and handling, including
 2831 a description of their duties and a summary of their
 2832 qualifications.

2833 (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A
 2834 wholesale ~~drug~~ distributor must operate in compliance with
 2835 applicable federal, state, and local laws and regulations.

PCB HCC 08-15

ORIGINAL

YEAR

2836 (a) A wholesale ~~drug~~ distributor must allow the department
 2837 and authorized federal, state, and local officials to enter and
 2838 inspect its premises and delivery vehicles, and to audit its
 2839 records and written operating procedures, at reasonable times and
 2840 in a reasonable manner, to the extent authorized by law.

2841 (b) A wholesale ~~drug~~ distributor that deals in controlled
 2842 substances must register with the Drug Enforcement Administration
 2843 and must comply with all applicable state, local, and federal
 2844 laws. A wholesale ~~drug~~ distributor that distributes any substance
 2845 controlled under chapter 893 must notify the department when
 2846 registering with the Drug Enforcement Administration pursuant to
 2847 that chapter and must provide the department with its DEA number.

2848 (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~
 2849 distributor is subject to any applicable federal, state, or local
 2850 laws or regulations that relate to prescription drug product
 2851 salvaging or reprocessing.

2852 (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person
 2853 responsible for shipment and transportation of a prescription
 2854 drug in a wholesale distribution may use a common carrier; its
 2855 own vehicle or employee acting within the scope of employment if
 2856 authorized under s. 499.03 for the possession of prescription
 2857 drugs in this state; or, in the case of a prescription drug
 2858 intended for domestic distribution, an independent contractor who
 2859 must be the agent of the authorized seller or recipient
 2860 responsible for shipping and transportation as set forth in a
 2861 written contract between the parties. A person selling a
 2862 prescription drug for export must obtain documentation, such as a
 2863 validated airway bill, bill of lading, or other appropriate
 2864 documentation that the prescription drug was exported. A person

PCB HCC 08-15

ORIGINAL

YEAR

2865 responsible for shipping or transporting prescription drugs is
 2866 not required to maintain documentation from a common carrier that
 2867 the designated recipient received the prescription drugs;
 2868 however, the person must obtain such documentation from the
 2869 common carrier and make it available to the department upon
 2870 request of the department.

2871 (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing
 2872 any prescription drugs from another wholesale ~~drug~~ distributor, a
 2873 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
 2874 state prescription drug wholesale distributor ~~wholesaler~~, or a
 2875 prescription drug repackager must:

2876 (a) Enter an agreement with the selling wholesale ~~drug~~
 2877 distributor by which the selling wholesale ~~drug~~ distributor will
 2878 indemnify the purchasing wholesale ~~drug~~ distributor for any loss
 2879 caused to the purchasing wholesale ~~drug~~ distributor related to
 2880 the purchase of drugs from the selling wholesale ~~drug~~ distributor
 2881 which are determined to be counterfeit or to have been
 2882 distributed in violation of any federal or state law governing
 2883 the distribution of drugs.

2884 (b) Determine that the selling wholesale ~~drug~~ distributor
 2885 has insurance coverage of not less than the greater of 1 percent
 2886 of the amount of total dollar volume of the prescription drug
 2887 sales reported to the department under s. 499.012(8)~~(3)~~(g) or
 2888 \$500,000; however the coverage need not exceed \$2 million.

2889 (c) Obtain information from the selling wholesale ~~drug~~
 2890 distributor, including the length of time the selling wholesale
 2891 ~~drug~~ distributor has been licensed in this state, a copy of the
 2892 selling wholesale ~~drug~~ distributor's licenses or permits, and
 2893 background information concerning the ownership of the selling

PCB HCC 08-15

ORIGINAL

YEAR

2894 wholesale ~~drug~~ distributor, including the experience of the
 2895 wholesale distributor in the wholesale distribution of
 2896 prescription drugs.

2897 (d) Verify that the selling wholesale ~~drug~~ distributor's
 2898 Florida permit is valid.

2899 (e) Inspect the selling wholesale ~~drug~~ distributor's
 2900 licensed establishment to document that it has a policies and
 2901 procedures manual relating to the distribution of drugs, the
 2902 appropriate temperature controlled environment for drugs
 2903 requiring temperature control, an alarm system, appropriate
 2904 access restrictions, and procedures to ensure that records
 2905 related to the wholesale distribution of prescription drugs are
 2906 maintained as required by law:

2907 1. Before purchasing any drug from the wholesale ~~drug~~
 2908 distributor, and at least once each subsequent year; or

2909 2. Before purchasing any drug from the wholesale ~~drug~~
 2910 distributor, and each subsequent year obtain a complete copy of
 2911 the most recent inspection report for the establishment which was
 2912 prepared by the department or the regulatory authority
 2913 responsible for wholesale ~~drug~~ distributors in the state in which
 2914 the establishment is located.

2915 Section 14. Section 499.012111, Florida Statutes, is
 2916 created to read:

2917 499.012111 Pedigree Paper.--

2918 (1) APPLICATION.--Each person who is engaged in the
 2919 wholesale distribution of a prescription drug must, prior to or
 2920 simultaneous with each wholesale distribution, provide a pedigree
 2921 paper to the person who receives the drug.

PCB HCC 08-15

ORIGINAL

YEAR

2922 (2) FORMAT.--A pedigree paper must contain the following
 2923 information:
 2924 (a) For the wholesale distribution of a prescription drug
 2925 within the normal distribution chain:
 2926 1. The following statement: "This wholesale distributor
 2927 purchased the specific unit of the prescription drug directly
 2928 from the manufacturer."
 2929 2. The manufacturer's national drug code identifier and the
 2930 name and address of the wholesale distributor and the purchaser
 2931 of the prescription drug.
 2932 3. The name of the prescription drug as it appears on the
 2933 label.
 2934 4. The quantity, dosage form, and strength of the
 2935 prescription drug.
 2936
 2937 The wholesale distributor must also maintain and make available
 2938 to the department, upon request, the point of origin of the
 2939 prescription drugs, including intracompany transfers; the date of
 2940 the shipment from the manufacturer to the wholesale distributor;
 2941 the lot numbers of such drugs; and the invoice numbers from the
 2942 manufacturer.
 2943 (b) For all other wholesale distributions of prescription
 2944 drugs, the:
 2945 1. Quantity, dosage form, and strength of the prescription
 2946 drugs.
 2947 2. Lot numbers of the prescription drugs.
 2948 3. The name and address of each owner of the prescription
 2949 drug and his or her signature.

PCB HCC 08-15

ORIGINAL

YEAR

2950 4. Shipping information, including the name and address of
 2951 each person certifying delivery or receipt of the prescription
 2952 drug.

2953 5. An invoice number, a shipping document number, or
 2954 another number uniquely identifying the transaction.

2955 6. A certification that the recipient wholesale distributor
 2956 has authenticated the pedigree papers.

2957 7. Unique serialization of the prescription drug, if the
 2958 manufacturer or repackager has uniquely serialized the individual
 2959 prescription drug unit.

2960 8. The name, address, telephone number and, if available,
 2961 e-mail contact information of each wholesale distributor involved
 2962 in the chain of the prescription drug's custody.

2963 (3) EXCEPTIONS.--A pedigree paper is not required for:

2964 (a) The wholesale distribution of a prescription drug by
 2965 the manufacturer.

2966 (b) The wholesale distribution of a compressed medical gas.

2967 (c) The wholesale distribution of a veterinary prescription
 2968 drug.

2969 (d) A drop shipment, provided that:

2970 1. The wholesale distributor delivers to the recipient of
 2971 the prescription drug, within 14 days after the shipment
 2972 notification from the manufacturer, an invoice and the following
 2973 sworn statement: "This wholesale distributor purchased the
 2974 specific unit of the prescription drug listed on the invoice
 2975 directly from the manufacturer, and the specific unit of
 2976 prescription drug was shipped by the manufacturer directly to a
 2977 person authorized by law administer or dispense the legend drug,
 2978 as defined in s. 465.003, Florida Statutes, or a member of an

PCB HCC 08-15

ORIGINAL

YEAR

2979 affiliated group, Florida Statutes, with the exception of a
 2980 repackager." The invoice must contain a unique cross-reference to
 2981 the shipping document sent by the manufacturer to the recipient
 2982 of the prescription drug.

2983 2. The manufacturer of the prescription drug shipped
 2984 directly to the recipient provides and the recipient of the
 2985 prescription drug acquires, within 14 days after receipt of the
 2986 prescription drug, a shipping document from the manufacturer that
 2987 contains, at a minimum:

2988 a. The name and address of the manufacturer, including the
 2989 point of origin of the shipment, and the names and addresses of
 2990 the wholesaler and the purchaser.

2991 b. The name of the prescription drug as it appears on the
 2992 label.

2993 c. The quantity, dosage form, and strength of the
 2994 prescription drug.

2995 d. The date of the shipment from the manufacturer.

2996 3. The wholesale distributor maintains and makes available
 2997 to the department, upon request, the lot number of such drug if
 2998 not contained in the shipping document acquired by the recipient.

3000 Failure of the manufacturer to provide, the recipient to acquire,
 3001 or the wholesale distributor to deliver, the documentation
 3002 required under paragraph (d) shall constitute failure to acquire
 3003 or deliver a pedigree paper under ss. 499.005(28) and 499.0051.

3004 Forgery by the manufacturer, the recipient, or the wholesale
 3005 distributor of the documentation required to be acquired or
 3006 delivered under paragraph (d) shall constitute forgery of a
 3007 pedigree paper under s. 499.0051.

PCB HCC 08-15

ORIGINAL

YEAR

3008 4. The wholesale distributor that takes title to, but not
 3009 possession of, the prescription drug is not a member of the
 3010 affiliated group that receives the prescription drug directly
 3011 from the manufacturer.

3012 (e) The wholesale distribution of a prescription drug by a
 3013 warehouse within an affiliated group to a warehouse or retail
 3014 pharmacy within its affiliated group, provided that:

3015 1. Any affiliated group member that purchases or receives a
 3016 prescription drug from outside the affiliated group must receive
 3017 a pedigree paper if the prescription drug is distributed in or
 3018 into this state and a pedigree paper is required under this
 3019 section and must authenticate the documentation as required in
 3020 subsection (4) of s. 499.0121, regardless of whether the
 3021 affiliated group member is directly subject to regulation under
 3022 this chapter; and

3023 2. The affiliated group makes available, within 48 hours,
 3024 to the department on request to one or more of its members all
 3025 records related to the purchase or acquisition of prescription
 3026 drugs by members of the affiliated group, regardless of the
 3027 location where the records are stored, if the prescription drugs
 3028 were distributed in or into this state.

3029 (f) The repackaging of prescription drugs by a repackager
 3030 solely for distribution to its affiliated group members for the
 3031 exclusive distribution to and among retail pharmacies that are
 3032 members of the affiliated group to which the repackager is a
 3033 member.

3034 1. The repackager must:

3035 a. For all repackaged prescription drugs distributed in or
 3036 into this state, state in writing under oath with each

PCB HCC 08-15

ORIGINAL

YEAR

3037 distribution of a repackaged prescription drug to an affiliated
 3038 group member warehouse or repackager: "All repackaged
 3039 prescription drugs are purchased by the affiliated group directly
 3040 from the manufacturer or from a prescription drug wholesale
 3041 distributor that purchased the prescription drugs directly from
 3042 the manufacturer.";

3043 b. Purchase all prescription drugs it repackages:
 3044 (I) Directly from the manufacturer; or
 3045 (II) From a prescription drug wholesaler that purchased the
 3046 prescription drugs directly from the manufacturer; and

3047 c. Maintain records in accordance with this section to
 3048 document that it purchased the prescription drugs directly from
 3049 the manufacturer or that its prescription drug wholesale supplier
 3050 purchased the prescription drugs directly from the manufacturer.

3051 2. All members of the affiliated group must provide, within
 3052 48 hours, to agents of the department on request to one or more
 3053 of its members records of purchases by all members of the
 3054 affiliated group of prescription drugs that have been repackaged,
 3055 regardless of the location where the records are stored or where
 3056 the repackager is located.

3057 Section 15. Section 499.0122, Florida Statutes, is
 3058 repealed.

3059 Section 16. Section 499.013, Florida Statutes, is repealed.

3060 Section 17. Section 499.015, Florida Statutes, is amended
 3061 to read:

3062 499.015 Registration of drugs, devices, and cosmetics;
 3063 issuance of certificates of free sale.--

3064 (1) (a) Except for those persons exempted from the
 3065 definition of manufacturer in s. 499.003 (32) ~~(28)~~, any person who

PCB HCC 08-15

ORIGINAL

YEAR

3066 manufactures, packages, repackages, labels, or relabels a drug,
 3067 device, or cosmetic in this state must register such drug,
 3068 device, or cosmetic biennially with the department; pay a fee in
 3069 accordance with the fee schedule provided by s. 499.041; and
 3070 comply with this section. The registrant must list each separate
 3071 and distinct drug, device, or cosmetic at the time of
 3072 registration.

3073 (b) The department may not register any product that does
 3074 not comply with the Federal Food, Drug, and Cosmetic Act, as
 3075 amended, or Title 21 C.F.R. Registration of a product by the
 3076 department does not mean that the product does in fact comply
 3077 with all provisions of the Federal Food, Drug, and Cosmetic Act,
 3078 as amended.

3079 (2) The department may require the submission of a catalog
 3080 and specimens of labels at the time of application for
 3081 registration of drugs, devices, and cosmetics packaged and
 3082 prepared in compliance with the federal act, which submission
 3083 constitutes a satisfactory compliance for registration of the
 3084 products. With respect to all other drugs, devices, and
 3085 cosmetics, the department may require the submission of a catalog
 3086 and specimens of labels at the time of application for
 3087 registration, but the registration will not become effective
 3088 until the department has examined and approved the label of the
 3089 drug, device, or cosmetic product. This approval or denial must
 3090 include written notification to the manufacturer.

3091 (3) Except for those persons exempted from the definition
 3092 of manufacturer in s. 499.003 (32) ~~(28)~~, a person may not sell any
 3093 product that he or she has failed to register in conformity with
 3094 this section. Such failure to register subjects such drug,

PCB HCC 08-15

ORIGINAL

YEAR

3095 | device, or cosmetic product to seizure and condemnation as
 3096 | provided in ss. 499.062-499.064, and subjects such person to the
 3097 | penalties and remedies provided in this part ~~ss. 499.001-499.081~~.

3098 | (4) Unless a registration is renewed, it expires 2 years
 3099 | after the last day of the month in which it was issued. The
 3100 | department may issue a stop-sale notice or order against a person
 3101 | that is subject to the requirements of this section and that
 3102 | fails to comply with this section within 31 days after the date
 3103 | the registration expires. The notice or order shall prohibit such
 3104 | person from selling or causing to be sold any drugs, devices, or
 3105 | cosmetics covered by this part ~~ss. 499.001-499.081~~ until he or
 3106 | she complies with the requirements of this section.

3107 | (5) A product regulated under this section which is not
 3108 | included in the biennial registration may not be sold until it is
 3109 | registered and complies with this section.

3110 | (6) The department may issue a certificate of free sale for
 3111 | any product that is required to be registered under this part ~~ss.~~
 3112 | ~~499.001-499.081~~.

3113 | (7) A product registration is valid only for the company
 3114 | named on the registration and located at the address on the
 3115 | registration. A person whose product is registered by the
 3116 | department under this section must notify the department before
 3117 | any change in the name or address of the establishment to which
 3118 | the product is registered. If a person whose product is
 3119 | registered ceases conducting business, the person must notify the
 3120 | department before closing the business.

3121 | (8) Notwithstanding any requirements set forth in this part
 3122 | ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is

PCB HCC 08-15

ORIGINAL

YEAR

3123 registered with the federal Food and Drug Administration is
 3124 exempt from this section and s. 499.041(6) if:

3125 (a) The manufacturer's medical devices are approved for
 3126 marketing by, or listed with the federal Food and Drug
 3127 Administration in accordance with federal law for commercial
 3128 distribution; or

3129 (b) The manufacturer subcontracts with a manufacturer of
 3130 medical devices to manufacture components of such devices.

3131 (9) However, the manufacturer must submit evidence of such
 3132 registration, listing, or approval with its initial application
 3133 for a permit to do business in this state, as required in s.
 3134 499.013 and any changes to such information previously submitted
 3135 at the time of renewal of the permit. Evidence of approval,
 3136 listing, and registration by the federal Food and Drug
 3137 Administration must include:

3138 (a) For Class II devices, a copy of the pre-market
 3139 notification letter (510K);

3140 (b) For Class III devices, a Federal Drug Administration
 3141 pre-market approval number;

3142 (c) For a manufacturer who subcontracts with a manufacturer
 3143 of medical devices to manufacture components of such devices, a
 3144 Federal Drug Administration registration number; or

3145 (d) For a manufacturer of medical devices whose devices are
 3146 exempt from pre-market approval by the Federal Drug
 3147 Administration, a Federal Drug Administration registration
 3148 number.

3149 Section 18. Section 499.023, Florida Statutes, is amended
 3150 to read:

PCB HCC 08-15

ORIGINAL

YEAR

3151 499.023 New drugs; sale, manufacture, repackaging,
 3152 distribution.--A person may not sell, offer for sale, hold for
 3153 sale, manufacture, repackage, distribute, or give away any new
 3154 drug unless an approved application has become effective under s.
 3155 505 of the federal act or unless otherwise permitted by the
 3156 Secretary of the United States Department of Health and Human
 3157 Services for shipment in interstate commerce.

3158 Section 19. Section 499.024, Florida Statutes, is amended
 3159 to read:

3160 499.024 Drug product classification.--The State Surgeon
 3161 General shall adopt rules to classify drug products intended for
 3162 use by humans which the United States Food and Drug
 3163 Administration has not classified in the federal act or the Code
 3164 of Federal Regulations.

3165 (1) Drug products must be classified as proprietary,
 3166 prescription, or investigational drugs.

3167 (2) If a product is distributed without required labeling,
 3168 it is misbranded while held for sale.

3169 (3) Any product that falls under the definition of drug in
 3170 ~~definition~~, s. 499.003(19) ~~(17)~~, may be classified under the
 3171 authority of this section. This section does not subject portable
 3172 emergency oxygen inhalators to classification; however, this
 3173 section does not exempt any person from ss. 499.01 and 499.015.

3174 (4) Any product classified under the authority of this
 3175 section reverts to the federal classification, if different, upon
 3176 the federal regulation or act becoming effective.

3177 (5) The department may by rule reclassify drugs subject to
 3178 this part ~~ss. 499.001-499.001~~ when such classification action is
 3179 necessary to protect the public health.

PCB HCC 08-15

ORIGINAL

YEAR

3180 (6) The department may adopt rules that exempt from any
 3181 labeling or packaging requirements of this part ~~ss. 499.001-~~
 3182 ~~499.001~~ drugs classified under this section if those requirements
 3183 are not necessary to protect the public health.

3184 Section 20. Section 499.025, Florida Statutes, is amended
 3185 to read:

3186 499.025 Drug products in finished, solid, oral dosage form;
 3187 identification requirements.--

3188 (1) A drug product in finished, solid, oral dosage form for
 3189 which a prescription is required by federal or state law may not
 3190 be manufactured or distributed within this state unless it is
 3191 clearly and prominently marked or imprinted with an individual
 3192 symbol, number, company name, words, letters, marking, or
 3193 national drug code, or any combination thereof, that identifies
 3194 the drug product and the manufacturer or distributor of the drug
 3195 product which has the ability to respond to requests for
 3196 information regarding the drug product.

3197 (2) A manufacturer or distributor must make available to
 3198 the department on request descriptive material that identifies
 3199 each current imprint used by the manufacturer.

3200 (3) The department, upon application by a manufacturer, may
 3201 exempt a particular drug product from the requirements of
 3202 subsection (1) on the ground that imprinting is not feasible
 3203 because of the size, texture, or other unique characteristic of
 3204 the drug product.

3205 (4) This section does not apply to drug products compounded
 3206 by a pharmacist licensed under chapter 465 in a pharmacy
 3207 operating under a permit issued by the Board of Pharmacy.

PCB HCC 08-15

ORIGINAL

YEAR

3208 (5) The department shall adopt rules for implementing this
 3209 section.

3210 Section 21. Section 499.028, Florida Statutes, is amended
 3211 to read:

3212 499.028 Drug samples or complimentary drugs; starter packs;
 3213 permits to distribute.--

3214 (1) As used in this section, the term:

3215 (a) "Drug sample," or "complimentary drug," means a human
 3216 prescription drug that is labeled "sample," "not to be sold,"
 3217 "complimentary," or other words to that effect, that is provided
 3218 as a courtesy, that is not intended to be sold, and that is
 3219 intended to promote the sale of the drug.

3220 (b) "Starter packs," also known as "stock samples," "trade
 3221 packages," "initial dose packs," or "starter stocks," means human
 3222 prescription drugs that are generally distributed without charge
 3223 by manufacturers or distributors to pharmacies to be placed in
 3224 stock and sold at retail. Although starter packs are generally
 3225 given without charge to the pharmacy, they are not intended to be
 3226 a free sample to the consumer nor are they labeled as such.
 3227 Starter packs are subject to regulation as prescription drugs
 3228 under the Florida Drug and Cosmetic Act in the same manner as
 3229 stock shipments of prescription drugs. Starter packs are not drug
 3230 samples.

3231 (2) A person may not sell, purchase, or trade or offer to
 3232 sell, purchase, or trade any drug sample. An officer or executive
 3233 of a drug manufacturer or distributor is not subject to criminal
 3234 liability solely because of a sale, purchase, trade, or offer to
 3235 sell, purchase, or trade of a drug sample in violation of this
 3236 subsection by other employees of the manufacturer or distributor.

PCB HCC 08-15

ORIGINAL

YEAR

3237 (3) Except as provided in this section, a representative of
 3238 a drug manufacturer or distributor may not distribute any drug
 3239 sample.

3240 (a) The manufacturer or distributor of a human prescription
 3241 drug may, in accordance with this paragraph, distribute drug
 3242 samples by mail or common carrier to practitioners licensed to
 3243 prescribe such drugs or, at the request of a licensed
 3244 practitioner, to pharmacies of hospitals or to pharmacies of
 3245 other health care entities. Such a distribution of drug samples
 3246 may only be made:

3247 1. In response to a written request for drug samples made
 3248 on a form that meets the requirements of paragraph (b); and

3249 2. Under a system that requires the recipient of the drug
 3250 sample to execute a written receipt for the drug sample upon its
 3251 delivery and to return the receipt to the manufacturer or
 3252 distributor.

3253 (b) A written request for a drug sample that is required by
 3254 this section must contain:

3255 1. The name, address, professional designation, and
 3256 signature of the practitioner who makes the request;

3257 2. The name, strength, and dosage form of the drug sample
 3258 requested and the quantity requested;

3259 3. The name of the manufacturer of the drug sample
 3260 requested; and

3261 4. The date of the request.

3262 (c) Each drug manufacturer or distributor that makes
 3263 distributions by mail or common carrier under this paragraph must
 3264 maintain, for a period of 3 years, the request forms submitted
 3265 for such distributions and the receipts submitted for such

PCB HCC 08-15

ORIGINAL

YEAR

3266 | distributions and must maintain a record of distributions of drug
 3267 | samples which identifies the drugs distributed and the recipients
 3268 | of the distributions. Forms, receipts, and records required to be
 3269 | maintained under this paragraph must be made available by the
 3270 | drug manufacturer or distributor to the department for its review
 3271 | and inspection.

3272 | (d) The manufacturer or distributor of a drug subject to
 3273 | paragraph (1)(a) may, by means other than mail or common carrier,
 3274 | distribute drug samples only if the manufacturer or distributor
 3275 | makes the distributions in accordance with paragraph (e) and
 3276 | carries out the activities described in subsections (4)-(9).

3277 | (e) Drug samples may only be distributed:

3278 | 1. To a practitioner authorized by law to prescribe such
 3279 | drugs if the practitioner makes a written request for the drug
 3280 | samples; or

3281 | 2. At the written request of such a practitioner, to
 3282 | pharmacies of hospitals or to pharmacies of other health care
 3283 | entities. The written request for drug samples must be made on a
 3284 | form that contains the practitioner's name, address, and
 3285 | professional designation, the name, strength, and dosage form of
 3286 | the drug sample requested, the quantity of drug samples
 3287 | requested, the name of the manufacturer or distributor of the
 3288 | drug sample, the date of the request, and the signature of the
 3289 | practitioner that makes the request.

3290 | (4) A drug manufacturer or distributor must store drug
 3291 | samples under the conditions described on their labels that will
 3292 | maintain the stability, integrity, and effectiveness of the drug
 3293 | samples and will assure that the drug samples remain free of
 3294 | contamination, deterioration, and adulteration.

PCB HCC 08-15

ORIGINAL

YEAR

3295 | (5) A drug manufacturer or distributor must conduct, at
 3296 | least annually, a complete and accurate inventory of all drug
 3297 | samples in the possession of representatives of the manufacturer
 3298 | or distributor. A drug manufacturer or distributor must maintain
 3299 | lists of the names and addresses of each of its representatives
 3300 | who distribute drug samples and of the sites where drug samples
 3301 | are stored. A drug manufacturer or distributor must maintain for
 3302 | at least 3 years records of all drug samples distributed,
 3303 | destroyed, or returned to the manufacturer or distributor, of all
 3304 | inventories maintained under this subsection, of all thefts or
 3305 | significant losses of drug samples, and of all requests made
 3306 | under subparagraph 1. for drug samples. The drug manufacturer or
 3307 | distributor must make available to the department upon request
 3308 | any record or list maintained under this subsection. The
 3309 | department shall provide to the Department of Business and
 3310 | Professional Regulation the names of those practitioners who have
 3311 | received an excessive or inappropriate quantity of such drugs.
 3312 | (6) A drug manufacturer or distributor must notify the
 3313 | department of any significant loss of drug samples and any known
 3314 | theft of drug samples.
 3315 | (7) A drug manufacturer or distributor must report to the
 3316 | department any conviction of itself or of its assigns, agents,
 3317 | employees, or representatives for a violation of s. 503(c)(1) of
 3318 | the federal act or of this part ~~ss. 499.001-499.081~~ because of
 3319 | the sale, purchase, or trade of a drug sample or the offer to
 3320 | sell, purchase, or trade a drug sample.
 3321 | (8) Drug manufacturers or distributors must provide to the
 3322 | department the name and telephone number of the individual

PCB HCC 08-15

ORIGINAL

YEAR

3323 responsible for responding to a request for information regarding
3324 drug samples.

3325 (9) All out-of-date drug samples must be returned to the
3326 manufacturer or distributor of that drug sample.

3327 (10) A manufacturer or distributor may not directly or
3328 through its agents, employees, or independent contractors, hold,
3329 distribute, or otherwise dispose of any complimentary drugs or
3330 drug samples in this state without first obtaining a
3331 complimentary drug distributor permit pursuant to this section.

3332 (11) (a) Application for a permit by a manufacturer or
3333 distributor to hold, distribute, or otherwise dispose of drugs
3334 pursuant to this section must be made on a form prescribed by the
3335 department and must be accompanied by an application fee in an
3336 amount not exceeding \$250 per year, as is determined by the
3337 department.

3338 (b) A permit issued under this section expires 2 years
3339 after the date of issuance, unless sooner suspended or revoked.

3340 (c) A permit is renewable biennially upon the filing of an
3341 application for renewal and the payment of a renewal fee of not
3342 more than \$250 per year, as determined by the department, if the
3343 applicant meets the requirements established by this section and
3344 the rules adopted under this section.

3345 (12) The department may suspend or revoke a permit issued
3346 under this section, after giving notice and an opportunity to be
3347 heard pursuant to chapter 120, when:

3348 (a) Such permit was obtained by misrepresentation or fraud
3349 or through a mistake of the department.

3350 (b) The holder of the permit has distributed or disposed of
3351 any prescription ~~legend~~ drug, directly or through its agents,

PCB HCC 08-15

ORIGINAL

YEAR

3352 employees, or independent contractors, to any person not
 3353 authorized to possess such drug.

3354 (c) The holder of the permit, or its agents, employees, or
 3355 independent contractors, has distributed or possessed any
 3356 prescription ~~legend~~ drug except in the usual course of its
 3357 business.

3358 (d) The holder of the permit, or its agents, employees, or
 3359 independent contractors, has distributed any prescription ~~legend~~
 3360 drug that is misbranded or adulterated under this part ~~ss-~~
 3361 ~~499.001-499.081~~.

3362 (e) The holder of the permit, or its agents, employees, or
 3363 independent contractors, has distributed any prescription ~~legend~~
 3364 drug without written request, when a written request is required
 3365 by this section.

3366 (f) The holder of the permit has in its employ, or uses as
 3367 agent or independent contractor for the purpose of distributing
 3368 or disposing of drugs, any person who has:

3369 1. Violated the requirements of this section or any rule
 3370 adopted under this section.

3371 2. Been convicted in any of the courts of this state, the
 3372 United States, or any other state of a felony or any other crime
 3373 involving moral turpitude or involving those drugs named or
 3374 described in chapter 893.

3375 (13) The department may, pursuant to chapter 120, impose an
 3376 administrative fine, not to exceed \$5,000 per violation per day,
 3377 for the violation of this section or rules adopted under this
 3378 section. Each day such violation continues constitutes a separate
 3379 violation, and each such separate violation is subject to a
 3380 separate fine. All amounts collected under this section shall be

PCB HCC 08-15

ORIGINAL

YEAR

3381 deposited into the Drug, Device, and Cosmetic Trust Fund. In
 3382 determining the amount of fine to be levied for a violation, the
 3383 following factors must be considered:

3384 (a) The severity of the violation.

3385 (b) Any actions taken by the permittee to correct the
 3386 violation or to remedy complaints.

3387 (c) Any previous violations.

3388 (14) Chapter 893 applies to all drug samples that are
 3389 controlled substances.

3390 (15) A person may not possess a prescription drug sample
 3391 unless:

3392 (a) The drug sample was prescribed to her or him as
 3393 evidenced by the label required in s. 465.0276(5).

3394 (b) She or he is the employee of a complimentary drug
 3395 distributor that holds a permit issued under this part ~~ss.~~
 3396 ~~499.001-499.081~~.

3397 (c) She or he is a person to whom prescription drug samples
 3398 may be distributed pursuant to this section.

3399 (d) He or she is an officer or employee of a federal,
 3400 state, or local government acting within the scope of his or her
 3401 employment.

3402 Section 22. Section 499.029, Florida Statutes, is amended
 3403 to read:

3404 499.029 Cancer Drug Donation Program.--

3405 (1) This section may be cited as the "Cancer Drug Donation
 3406 Program Act."

3407 (2) There is created a Cancer Drug Donation Program within
 3408 the department ~~of Health~~ for the purpose of authorizing and

PCB HCC 08-15

ORIGINAL

YEAR

3409 | facilitating the donation of cancer drugs and supplies to
 3410 | eligible patients.

3411 | (3) As used in this section:

3412 | (a) "Cancer drug" means a prescription drug that has been
 3413 | approved under s. 505 of the federal Food, Drug, and Cosmetic Act
 3414 | and is used to treat cancer or its side effects or is used to
 3415 | treat the side effects of a prescription drug used to treat
 3416 | cancer or its side effects. "Cancer drug" does not include a
 3417 | substance listed in Schedule II, Schedule III, Schedule IV, or
 3418 | Schedule V of s. 893.03.

3419 | (b) "Closed drug delivery system" means a system in which
 3420 | the actual control of the unit-dose medication package is
 3421 | maintained by the facility rather than by the individual patient.

3422 | ~~(c) "Department" means the Department of Health.~~

3423 | (c) ~~(d)~~ "Donor" means a patient or patient representative
 3424 | who donates cancer drugs or supplies needed to administer cancer
 3425 | drugs that have been maintained within a closed drug delivery
 3426 | system; health care facilities, nursing homes, hospices, or
 3427 | hospitals with closed drug delivery systems; or pharmacies, drug
 3428 | manufacturers, medical device manufacturers or suppliers, or
 3429 | wholesalers of drugs or supplies, in accordance with this
 3430 | section. "Donor" includes a physician licensed under chapter 458
 3431 | or chapter 459 who receives cancer drugs or supplies directly
 3432 | from a drug manufacturer, drug wholesaler, or pharmacy.

3433 | (d) ~~(e)~~ "Eligible patient" means a person who the department
 3434 | determines is eligible to receive cancer drugs from the program.

3435 | (e) ~~(k)~~ "Participant facility" means a class II hospital
 3436 | pharmacy that has elected to participate in the program and that

PCB HCC 08-15

ORIGINAL

YEAR

3437 | accepts donated cancer drugs and supplies under the rules adopted
 3438 | by the department for the program.

3439 | ~~(e)~~ "Prescription drug" means a drug as defined in s.
 3440 | 465.003(8).

3441 | (f)~~(p)~~ "Program" means the Cancer Drug Donation Program
 3442 | created by this section.

3443 | (g)~~(q)~~ "Supplies" means any supplies used in the
 3444 | administration of a cancer drug.

3445 | (4) Any donor may donate cancer drugs or supplies to a
 3446 | participant facility that elects to participate in the program
 3447 | and meets criteria established by the department for such
 3448 | participation. Cancer drugs or supplies may not be donated to a
 3449 | specific cancer patient, and donated drugs or supplies may not be
 3450 | resold by the program. Cancer drugs billed to and paid for by
 3451 | Medicaid in long-term care facilities that are eligible for
 3452 | return to stock under federal Medicaid regulations shall be
 3453 | credited to Medicaid and are not eligible for donation under the
 3454 | program. A participant facility may provide dispensing and
 3455 | consulting services to individuals who are not patients of the
 3456 | hospital.

3457 | (5) The cancer drugs or supplies donated to the program may
 3458 | be prescribed only by a prescribing practitioner for use by an
 3459 | eligible patient and may be dispensed only by a pharmacist.

3460 | (6) (a) A cancer drug may only be accepted or dispensed
 3461 | under the program if the drug is in its original, unopened,
 3462 | sealed container, or in a tamper-evident unit-dose packaging,
 3463 | except that a cancer drug packaged in single-unit doses may be
 3464 | accepted and dispensed if the outside packaging is opened but the

PCB HCC 08-15

ORIGINAL

YEAR

3465 single-unit-dose packaging is unopened with tamper-resistant
 3466 packaging intact.

3467 (b) A cancer drug may not be accepted or dispensed under
 3468 the program if the drug bears an expiration date that is less
 3469 than 6 months after the date the drug was donated or if the drug
 3470 appears to have been tampered with or mislabeled as determined in
 3471 paragraph (c).

3472 (c) Prior to being dispensed to an eligible patient, the
 3473 cancer drug or supplies donated under the program shall be
 3474 inspected by a pharmacist to determine that the drug and supplies
 3475 do not appear to have been tampered with or mislabeled.

3476 (d) A dispenser of donated cancer drugs or supplies may not
 3477 submit a claim or otherwise seek reimbursement from any public or
 3478 private third-party payor for donated cancer drugs or supplies
 3479 dispensed to any patient under the program, and a public or
 3480 private third-party payor is not required to provide
 3481 reimbursement to a dispenser for donated cancer drugs or supplies
 3482 dispensed to any patient under the program.

3483 (7) (a) A donation of cancer drugs or supplies shall be made
 3484 only at a participant facility. A participant facility may
 3485 decline to accept a donation. A participant facility that accepts
 3486 donated cancer drugs or supplies under the program shall comply
 3487 with all applicable provisions of state and federal law relating
 3488 to the storage and dispensing of the donated cancer drugs or
 3489 supplies.

3490 (b) A participant facility that voluntarily takes part in
 3491 the program may charge a handling fee sufficient to cover the
 3492 cost of preparation and dispensing of cancer drugs or supplies

PCB HCC 08-15

ORIGINAL

YEAR

3493 | under the program. The fee shall be established in rules adopted
 3494 | by the department.

3495 | (8) The department, upon the recommendation of the Board of
 3496 | Pharmacy, shall adopt rules to carry out the provisions of this
 3497 | section. Initial rules under this section shall be adopted no
 3498 | later than 90 days after the effective date of this act. The
 3499 | rules shall include, but not be limited to:

3500 | (a) Eligibility criteria, including a method to determine
 3501 | priority of eligible patients under the program.

3502 | (b) Standards and procedures for participant facilities
 3503 | that accept, store, distribute, or dispense donated cancer drugs
 3504 | or supplies.

3505 | (c) Necessary forms for administration of the program,
 3506 | including, but not limited to, forms for use by entities that
 3507 | donate, accept, distribute, or dispense cancer drugs or supplies
 3508 | under the program.

3509 | (d) The maximum handling fee that may be charged by a
 3510 | participant facility that accepts and distributes or dispenses
 3511 | donated cancer drugs or supplies.

3512 | (e) Categories of cancer drugs and supplies that the
 3513 | program will accept for dispensing; however, the department may
 3514 | exclude any drug based on its therapeutic effectiveness or high
 3515 | potential for abuse or diversion.

3516 | (f) Maintenance and distribution of the participant
 3517 | facility registry established in subsection (10).

3518 | (9) A person who is eligible to receive cancer drugs or
 3519 | supplies under the state Medicaid program or under any other
 3520 | prescription drug program funded in whole or in part by the
 3521 | state, by any other prescription drug program funded in whole or

PCB HCC 08-15

ORIGINAL

YEAR

3522 | in part by the Federal Government, or by any other prescription
 3523 | drug program offered by a third-party insurer, unless benefits
 3524 | have been exhausted, or a certain cancer drug or supply is not
 3525 | covered by the prescription drug program, is ineligible to
 3526 | participate in the program created under this section.

3527 | (10) The department shall establish and maintain a
 3528 | participant facility registry for the program. The participant
 3529 | facility registry shall include the participant facility's name,
 3530 | address, and telephone number. The department shall make the
 3531 | participant facility registry available on the department's
 3532 | website to any donor wishing to donate cancer drugs or supplies
 3533 | to the program. The department's website shall also contain links
 3534 | to cancer drug manufacturers that offer drug assistance programs
 3535 | or free medication.

3536 | (11) Any donor of cancer drugs or supplies, or any
 3537 | participant in the program, who exercises reasonable care in
 3538 | donating, accepting, distributing, or dispensing cancer drugs or
 3539 | supplies under the program and the rules adopted under this
 3540 | section shall be immune from civil or criminal liability and from
 3541 | professional disciplinary action of any kind for any injury,
 3542 | death, or loss to person or property relating to such activities.

3543 | (12) A pharmaceutical manufacturer is not liable for any
 3544 | claim or injury arising from the transfer of any cancer drug
 3545 | under this section, including, but not limited to, liability for
 3546 | failure to transfer or communicate product or consumer
 3547 | information regarding the transferred drug, as well as the
 3548 | expiration date of the transferred drug.

3549 | (13) If any conflict exists between the provisions in this
 3550 | section and the provisions in this chapter or chapter 465, the

PCB HCC 08-15

ORIGINAL

YEAR

3551 provisions in this section shall control the operation of the
 3552 Cancer Drug Donation Program.

3553 Section 23. Section 499.03, Florida Statutes, is amended to
 3554 read:

3555 499.03 Possession of certain drugs without prescriptions
 3556 unlawful; exemptions and exceptions.--

3557 (1) A person may not possess, or possess with intent to
 3558 sell, dispense, or deliver, any habit-forming, toxic, harmful, or
 3559 new drug subject to s. 499.003(33)~~(29)~~, or prescription legend~~legend~~
 3560 drug as defined in s. 499.003(44)~~(25)~~, unless the possession of
 3561 the drug has been obtained by a valid prescription of a
 3562 practitioner licensed by law to prescribe the drug. However, this
 3563 section does not apply to the delivery of such drugs to persons
 3564 included in any of the classes named in this subsection, or to
 3565 the agents or employees of such persons, for use in the usual
 3566 course of their businesses or practices or in the performance of
 3567 their official duties, as the case may be; nor does this section
 3568 apply to the possession of such drugs by those persons or their
 3569 agents or employees for such use:

3570 (a) A licensed pharmacist or any person under the licensed
 3571 pharmacist's supervision while acting within the scope of the
 3572 licensed pharmacist's practice;

3573 (b) A licensed practitioner authorized by law to prescribe
 3574 prescription legend~~legend~~ drugs or any person under the licensed
 3575 practitioner's supervision while acting within the scope of the
 3576 licensed practitioner's practice;

3577 (c) A qualified person who uses prescription legend~~legend~~ drugs
 3578 for lawful research, teaching, or testing, and not for resale;

PCB HCC 08-15

ORIGINAL

YEAR

3579 (d) A licensed hospital or other institution that procures
 3580 such drugs for lawful administration or dispensing by
 3581 practitioners;

3582 (e) An officer or employee of a federal, state, or local
 3583 government; or

3584 (f) A person that holds a valid permit issued by the
 3585 department pursuant to this part that ss. 499.001-499.081 which
 3586 authorizes that person to possess prescription drugs.

3587 (2) The possession of a drug under subsection (1) by any
 3588 person not exempted under this section, which drug is not
 3589 properly labeled to indicate that possession is by a valid
 3590 prescription of a practitioner licensed by law to prescribe such
 3591 drug, is prima facie evidence that such possession is unlawful.

3592 (3) Violation of subsection (1) is a misdemeanor of the
 3593 second degree, punishable as provided in s. 775.082 or s.
 3594 775.083, except that possession with the intent to sell,
 3595 dispense, or deliver is a third degree felony, punishable as
 3596 provided in s. 775.082, s. 775.083, or s. 775.084.

3597 (4) The department may adopt rules regarding persons
 3598 engaged in lawful teaching, research, or testing who possess
 3599 prescription drugs and may issue letters of exemption to
 3600 facilitate the lawful possession of prescription drugs under this
 3601 section.

3602 Section 24. Section 499.032, Florida Statutes, is amended
 3603 to read:

3604 499.032 Phenylalanine; prescription required.--
 3605 Phenylalanine restricted formula is declared to be a prescription
 3606 ~~legend~~ drug and may be dispensed only upon the prescription of a

PCB HCC 08-15

ORIGINAL

YEAR

3607 practitioner authorized by law to prescribe prescription
 3608 ~~medicinal~~ drugs.

3609 Section 25. Section 499.033, Florida Statutes, is amended
 3610 to read:

3611 499.033 Ephedrine; prescription required.--Ephedrine is
 3612 declared to be a prescription drug.

3613 (1) Except as provided in subsection (2), any product that
 3614 contains any quantity of ephedrine, a salt of ephedrine, an
 3615 optical isomer of ephedrine, or a salt of an optical isomer of
 3616 ephedrine may be dispensed only upon the prescription of a duly
 3617 licensed practitioner authorized by the laws of the state to
 3618 prescribe prescription ~~medicinal~~ drugs.

3619 (2) A product containing ephedrine described in paragraphs
 3620 (a)-(e) is exempt from subsection (1) if it may lawfully be sold
 3621 over the counter without a prescription under the federal act; is
 3622 labeled and marketed in a manner consistent with the pertinent
 3623 United States Food and Drug Administration Over-the-Counter
 3624 Tentative Final or Final Monograph; and is manufactured and
 3625 distributed for legitimate medicinal use in a manner that reduces
 3626 or eliminates the likelihood of abuse, when considered in the
 3627 context with: the package sizes and the manner of packaging of
 3628 the drug product; the name and labeling of the product; the
 3629 manner of distribution, advertising, and promotion of the
 3630 product; the duration, scope, health significance, and societal
 3631 cost of abuse of the particular product; the need to provide
 3632 medically important ephedrine-containing therapies to the public
 3633 for United States Food and Drug Administration approved
 3634 indications on an unrestricted, over-the-counter basis; and other

PCB HCC 08-15

ORIGINAL

YEAR

3635 facts as may be relevant to and consistent with public health and
3636 safety.

3637 (a) Solid oral dosage forms that combine active ingredients
3638 in the following ranges for each dosage unit:

3639 1. Theophylline (100-130mg), ephedrine (12.5-24mg).

3640 2. Theophylline (60-100mg), ephedrine (12.5-24mg),
3641 guaifenesin (200-400mg).

3642 3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).

3643 4. Phenobarbital (not greater than 8mg) in combination with
3644 the ingredients of subparagraph 1. or subparagraph 2.

3645 (b) Liquid oral dosage forms that combine active
3646 ingredients in the following ranges for each (5ml) dose:

3647 1. Theophylline (not greater than 45mg), ephedrine (not
3648 greater than 36mg), guaifenesin (not greater than 100mg),
3649 phenobarbital (not greater than 12mg).

3650 2. Phenylephrine (not greater than 5mg), ephedrine (not
3651 greater than 5mg), chlorpheniramine (not greater than 2mg),
3652 dextromethorphan (not greater than 10mg), ammonium chloride (not
3653 greater than 40mg), ipecac fluid extract (not greater than
3654 0.005ml).

3655 (c) Anorectal preparations containing less than 5 percent
3656 ephedrine.

3657 (d) Nasal decongestant compounds, mixtures, or preparations
3658 containing 0.5 percent or less ephedrine.

3659 (e) Any drug product containing ephedrine that is marketed
3660 pursuant to an approved new drug application or legal equivalent
3661 under the federal act.

3662 (3) The department may implement this section by rule.

PCB HCC 08-15

ORIGINAL

YEAR

3663 Section 26. Section 499.035, Florida Statutes, is amended
 3664 to read:

3665 499.035 Dimethyl sulfoxide (DMSO); labeling and
 3666 advertising.--

3667 (1) Dimethyl sulfoxide (DMSO) not approved for drug use
 3668 must be clearly marked in at least 12-point boldfaced type: "May
 3669 be unsafe. Not approved for human use."

3670 (2) All advertisements for the sale of dimethyl sulfoxide
 3671 (DMSO) not approved for drug use must contain, within the
 3672 advertisement and in bold lettering, the following statement:
 3673 "Warning. May be unsafe. Not approved for human use."

3674 Section 27. Section 499.039, Florida Statutes, is amended
 3675 to read:

3676 499.039 Sale, distribution, or transfer of harmful chemical
 3677 substances; penalties; authority for enforcement.--It is unlawful
 3678 for a person to sell, deliver, or give to a person under the age
 3679 of 18 years any compound, liquid, or chemical containing toluol,
 3680 hexane, trichloroethylene, acetone, toluene, ethyl acetate,
 3681 methyl ethyl ketone, trichloroethane, isopropanol, methyl
 3682 isobutyl ketone, ethylene glycol monomethyl ether acetate,
 3683 cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites
 3684 (butyl nitrite), or any similar substance for the purpose of
 3685 inducing by breathing, inhaling, or ingesting a condition of
 3686 intoxication or which is intended to distort or disturb the
 3687 auditory, visual, or other physical or mental processes.

3688 (1) On the first violation of this section, the department
 3689 may issue a warning according to s. 499.071, if the violation has
 3690 not caused temporary or permanent physical or mental injury to
 3691 the user.

PCB HCC 08-15

ORIGINAL

YEAR

3692 (2) If any violation of this section has caused temporary
 3693 or permanent physical or mental injury to the user, the
 3694 department may, pursuant to chapter 120, impose fines according
 3695 to s. 499.066 and may report any violation to the appropriate
 3696 state attorney for prosecution.

3697 (3) The department ~~of Health~~ shall adopt rules to implement
 3698 this section.

3699 Section 28. Section 499.04, Florida Statutes, is amended to
 3700 read:

3701 499.04 Fee authority.--The department may collect fees for
 3702 all drug, device, and cosmetic applications, permits, product
 3703 registrations, and free-sale certificates. The total amount of
 3704 fees collected from all permits, applications, product
 3705 registrations, and free-sale certificates must be adequate to
 3706 fund the expenses incurred by the department in carrying out this
 3707 part ~~ss. 499.001-499.081~~. The department shall, by rule,
 3708 establish a schedule of fees that are within the ranges provided
 3709 in this section and shall adjust those fees from time to time
 3710 based on the costs associated with administering this part ~~ss.~~
 3711 ~~499.001-499.081~~. The fees are payable to the department to be
 3712 deposited into the Florida Drug, Device, and Cosmetic Trust Fund
 3713 for the sole purpose of carrying out the provisions of this part
 3714 ~~ss. 499.001-499.081~~.

3715 Section 29. Section 499.041, Florida Statutes, is amended
 3716 to read:

3717 499.041 Schedule of fees for drug, device, and cosmetic
 3718 applications and permits, product registrations, and free-sale
 3719 certificates.--

PCB HCC 08-15

ORIGINAL

YEAR

3720 (1) The department shall assess applicants requiring a
 3721 manufacturing permit an annual fee within the ranges established
 3722 in this section for the specific type of manufacturer.

3723 (a) The fee for a prescription drug manufacturer
 3724 ~~manufacturer's~~ permit may not be less than \$500 or more than \$750
 3725 annually.

3726 (b) The fee for a device manufacturer's permit may not be
 3727 less than \$500 or more than \$600 annually.

3728 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~
 3729 permit may not be less than \$250 or more than \$400 annually.

3730 (d) The fee for an over-the-counter drug manufacturer
 3731 ~~manufacturer's~~ permit may not be less than \$300 or more than \$400
 3732 annually.

3733 (e) The fee for a compressed medical gas manufacturer
 3734 ~~manufacturer's~~ permit may not be less than \$400 or more than \$500
 3735 annually.

3736 (f) The fee for a prescription drug repackager ~~repackager's~~
 3737 permit may not be less than \$500 or more than \$750 annually.

3738 (g) A manufacturer may not be required to pay more than one
 3739 fee per establishment to obtain an additional manufacturing
 3740 permit, but each manufacturer must pay the highest fee applicable
 3741 to his or her operation in each establishment.

3742 (2) The department shall assess an applicant that is
 3743 required to have a wholesaling permit an annual fee within the
 3744 ranges established in this section for the specific type of
 3745 wholesaling.

3746 (a) The fee for a prescription drug wholesale distributor
 3747 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800
 3748 annually.

PCB HCC 08-15

ORIGINAL

YEAR

3749 (b) The fee for a compressed medical gas wholesale
 3750 distributor ~~wholesaler's~~ permit may not be less than \$200 or more
 3751 than \$300 annually.

3752 (c) The fee for an out-of-state prescription drug wholesale
 3753 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
 3754 than \$800 annually.

3755 (d) The fee for a nonresident prescription drug
 3756 manufacturer's permit may not be less than \$300 or more than \$500
 3757 annually.

3758 (e) The fee for a retail pharmacy wholesale distributor
 3759 ~~wholesaler's~~ permit may not be less than \$35 or more than \$50
 3760 annually.

3761 (f) The fee for a freight forwarder's permit may not be
 3762 less than \$200 or more than \$300 annually.

3763 (g) The fee for a veterinary prescription drug wholesale
 3764 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
 3765 than \$500 annually.

3766 (h) The fee for a limited prescription drug veterinary
 3767 wholesale distributor ~~wholesaler's~~ permit may not be less than
 3768 \$300 or more than \$500 annually.

3769 (3) The department shall assess an applicant that is
 3770 required to have a retail establishment permit an annual fee
 3771 within the ranges established in this section for the specific
 3772 type of retail establishment.

3773 (a) The fee for a veterinary prescription ~~legend~~ drug
 3774 retail establishment permit may not be less than \$200 or more
 3775 than \$300 annually.

3776 (b) The fee for a medical oxygen retail establishment
 3777 permit may not be less than \$200 or more than \$300 annually.

PCB HCC 08-15

ORIGINAL

YEAR

3778 (4) The department shall assess an applicant that is
 3779 required to have a restricted prescription drug distributor
 3780 ~~distributor's~~ permit an annual fee of not less than \$200 or more
 3781 than \$300.

3782 (5) In addition to the fee charged for a permit required by
 3783 this part ~~ss. 499.001-499.081~~, the department shall assess
 3784 applicants an initial application fee of \$150 for each new permit
 3785 issued by the department which requires an onsite inspection.

3786 (6) A person that is required to register drugs, devices,
 3787 or cosmetic products under s. 499.015 shall pay an annual product
 3788 registration fee of not less than \$5 or more than \$15 for each
 3789 separate and distinct product in package form. The registration
 3790 fee is in addition to the fee charged for a free-sale
 3791 certificate.

3792 (7) The department shall assess an applicant that requests
 3793 a free-sale certificate a fee of \$25. A fee of \$2 will be charged
 3794 for each signature copy of a free-sale certificate that is
 3795 obtained at the same time the free-sale certificate is issued.

3796 (8) The department shall assess an out-of-state
 3797 prescription drug wholesale distributor ~~wholesaler~~ applicant or
 3798 permittee an onsite inspection fee of not less than \$1,000 or
 3799 more than \$3,000 annually, to be based on the actual cost of the
 3800 inspection if an onsite inspection is performed by agents of the
 3801 department.

3802 (9) The department shall assess each person applying for
 3803 certification as a designated representative a fee of \$150, plus
 3804 the cost of processing the criminal history record check.

3805 (10) The department shall assess other fees as provided in
 3806 this part ~~ss. 499.001-499.081~~.

PCB HCC 08-15

ORIGINAL

YEAR

3807 Section 30. Section 499.05, Florida Statutes, is amended,
 3808 subsection (3) of section 499.013, Florida Statutes, is
 3809 renumbered as paragraph (1)(k) of that section and amended,
 3810 paragraph (2)(b) of section 499.0122, Florida Statutes, is
 3811 renumbered as paragraph (1)(l) of that section and amended, and
 3812 subsection (12) of section 499.012, Florida Statutes, is
 3813 renumbered as subsection (1)(m) of that section and amended, to
 3814 read:

3815 499.05 Rules.--

3816 (1) The department shall adopt rules to implement and
 3817 enforce this part ~~ss. 499.001-499.081~~ with respect to:

3818 (a) The definition of terms used in this part ~~ss. 499.001-~~
 3819 ~~499.081~~, and used in the rules adopted under this part ~~ss.~~
 3820 ~~499.001-499.081~~, when the use of the term is not its usual and
 3821 ordinary meaning.

3822 (b) Labeling requirements for drugs, devices, and
 3823 cosmetics.

3824 (c) The establishment of fees authorized in this part ~~ss.~~
 3825 ~~499.001-499.081~~.

3826 (d) The identification of permits that require an initial
 3827 application and onsite inspection or other prerequisites for
 3828 permitting which demonstrate that the establishment and person
 3829 are in compliance with the requirements of this part ~~ss. 499.001-~~
 3830 ~~499.081~~.

3831 (e) The application processes and forms for product
 3832 registration.

3833 (f) Procedures for requesting and issuing certificates of
 3834 free sale.

PCB HCC 08-15

ORIGINAL

YEAR

3835 (g) Inspections and investigations conducted under s.
 3836 499.051, and the identification of information claimed to be a
 3837 trade secret and exempt from the public records law as provided
 3838 in s. 499.051(7).

3839 (h) The establishment of a range of penalties, as provided
 3840 in s. 499.066 ~~499.006~~; requirements for notifying persons of the
 3841 potential impact of a violation of this part ~~ss. 499.001-499.081~~;
 3842 and a process for the uncontested settlement of alleged
 3843 violations.

3844 (i) Additional conditions that qualify as an emergency
 3845 medical reason under s. 499.003(55)(b)2. ~~499.012(1)(a)2.b.~~

3846 (j) Procedures and forms relating to the pedigree paper
 3847 requirement of s. 499.012111.

3848 ~~(k)(3) The department may adopt such rules as are necessary~~
 3849 ~~for~~ The protection of the public health, safety, and welfare
 3850 regarding good manufacturing practices that manufacturers and
 3851 repackagers must follow to ensure the safety of the products.

3852 ~~(l)(b) The department shall adopt rules relating to~~
 3853 Information required from each retail establishment pursuant to
 3854 s. 499.012(3) ~~499.01(4)~~, including requirements for prescriptions
 3855 or orders.

3856 ~~(m)(12) The department may adopt rules governing~~ The
 3857 recordkeeping, storage, and handling with respect to each of the
 3858 distributions of prescription drugs specified in ~~sub~~paragraphs
 3859 (55)(a)-(d) of s. 499.003 ~~(1)(a)1-4.~~

3860 (n) Alternatives to compliance with s. 499.012111 for a
 3861 prescription drug in the inventory of a permitted prescription
 3862 drug wholesale distributor as of June 30, 2006, and the return of

PCB HCC 08-15

ORIGINAL

YEAR

3863 | a prescription drug purchased prior to July 1, 2006. The
 3864 | department may specify time limits for such alternatives.

3865 | (2) With respect to products in interstate commerce, those
 3866 | rules must not be inconsistent with rules and regulations of
 3867 | federal agencies unless specifically otherwise directed by the
 3868 | Legislature.

3869 | (3) The department shall adopt rules regulating
 3870 | recordkeeping for and the storage, handling, and distribution of
 3871 | medical devices and over-the-counter drugs to protect the public
 3872 | from adulterated products.

3873 | Section 31. Section 499.051, Florida Statutes, is amended
 3874 | to read:

3875 | 499.051 Inspections and investigations.--

3876 | (1) The agents of the department ~~of Health~~ and of the
 3877 | Department of Law Enforcement, after they present proper
 3878 | identification, may inspect, monitor, and investigate any
 3879 | establishment permitted pursuant to this part ~~ss. 499.001-499.081~~
 3880 | during business hours for the purpose of enforcing this part ~~ss.~~
 3881 | ~~499.001-499.081~~, chapters 465, 501, and 893, and the rules of the
 3882 | department that protect the public health, safety, and welfare.

3883 | (2) In addition to the authority set forth in subsection
 3884 | (1), the department and any duly designated officer or employee
 3885 | of the department may enter and inspect any other establishment
 3886 | for the purpose of determining compliance with this part ~~ss.~~
 3887 | ~~499.001-499.081~~ and rules adopted under those sections regarding
 3888 | any drug, device, or cosmetic product.

3889 | (3) Any application for a permit or product registration or
 3890 | for renewal of such permit or registration made pursuant to this
 3891 | part ~~ss. 499.001-499.081~~ and rules adopted under those sections

PCB HCC 08-15

ORIGINAL

YEAR

3892 | constitutes permission for any entry or inspection of the
 3893 | premises in order to verify compliance with those sections and
 3894 | rules; to discover, investigate, and determine the existence of
 3895 | compliance; or to elicit, receive, respond to, and resolve
 3896 | complaints and violations.

3897 | (4) Any application for a permit made pursuant to ~~ss.~~
 3898 | ~~499.01 and 499.012~~ and rules adopted under those sections
 3899 | constitutes permission for agents of the department ~~of Health~~ and
 3900 | the Department of Law Enforcement, after presenting proper
 3901 | identification, to inspect, review, and copy any financial
 3902 | document or record related to the manufacture, repackaging, or
 3903 | distribution of a drug as is necessary to verify compliance with
 3904 | this part ~~ss. 499.001-499.081~~ and the rules adopted by the
 3905 | department to administer those sections, in order to discover,
 3906 | investigate, and determine the existence of compliance, or to
 3907 | elicit, receive, respond to, and resolve complaints and
 3908 | violations.

3909 | (5) The authority to inspect under this section includes
 3910 | the authority to access, review, and copy any and all financial
 3911 | documents related to the activity of manufacturing, repackaging,
 3912 | or distributing prescription drugs.

3913 | (6) The authority to inspect under this section includes
 3914 | the authority to secure:

3915 | (a) Samples or specimens of any drug, device, or cosmetic;
 3916 | or

3917 | (b) Such other evidence as is needed for any action to
 3918 | enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under
 3919 | those sections.

PCB HCC 08-15

ORIGINAL

YEAR

3920 (7) The complaint and all information obtained pursuant to
 3921 the investigation by the department are confidential and exempt
 3922 from the provisions of s. 119.07(1) and s. 24(a), Art. I of the
 3923 State Constitution until the investigation and the enforcement
 3924 action are completed. However, trade secret information contained
 3925 therein as defined by s. 812.081(1)(c) shall remain confidential
 3926 and exempt from the provisions of s. 119.07(1) and s. 24(a), Art.
 3927 I of the State Constitution, as long as the information is
 3928 retained by the department. This subsection does not prohibit the
 3929 department from using such information for regulatory or
 3930 enforcement proceedings under this chapter or from providing such
 3931 information to any law enforcement agency or any other regulatory
 3932 agency. However, the receiving agency shall keep such records
 3933 confidential and exempt as provided in this subsection. In
 3934 addition, this subsection is not intended to prevent compliance
 3935 with the provisions of s. 499.012111(6)(d), and the pedigree
 3936 papers required in that subsection shall not be deemed a trade
 3937 secret.

3938 Section 32. Section 499.052, Florida Statutes, is amended
 3939 to read:

3940 499.052 Records of interstate shipment.--For the purpose of
 3941 enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in
 3942 interstate commerce and persons receiving drugs, devices, or
 3943 cosmetics in interstate commerce must, upon the request, in the
 3944 manner set out below, by an officer or employee duly designated
 3945 by the department, permit the officer or employee to have access
 3946 to and to copy all records showing the movement in interstate
 3947 commerce of any drug, device, or cosmetic, and the quantity,
 3948 shipper, and consignee thereof.

PCB HCC 08-15

ORIGINAL

YEAR

3949 Section 33. Section 499.055, Florida Statutes, is amended
3950 to read:

3951 499.055 Reports and dissemination of information by
3952 department.--

3953 (1) The department may cause to be published from time to
3954 time reports summarizing all judgments, decrees, and court orders
3955 that have been rendered under ss. 499.001-499.79, including the
3956 nature of any charges and the dispositions of the charges.

3957 (2) The department may also cause to be disseminated such
3958 information regarding drugs, devices, and cosmetics as considered
3959 necessary in the interest of public health and the protection of
3960 consumers against fraud.

3961 (3) This section does not prohibit the department from
3962 collecting, reporting, and illustrating the results of its
3963 investigations.

3964 (4) The department shall publish on the department's
3965 website and update at least monthly:

3966 (a) A list of the prescription drug wholesale distributors
3967 ~~wholesalers~~, out-of-state prescription drug wholesale
3968 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
3969 distributors ~~wholesalers~~ against whom the department has
3970 initiated enforcement action pursuant to this part ~~ss. 499.001-~~
3971 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or
3972 otherwise file an administrative complaint and the permit number
3973 of each such wholesaler.

3974 (b) A list of the prescription drug wholesale distributors
3975 ~~wholesalers~~, out-of-state prescription drug wholesale
3976 distributors ~~wholesalers~~, and retail pharmacy drug wholesale

PCB HCC 08-15

ORIGINAL

YEAR

3977 distributors ~~wholesalers~~ to which the department has issued a
 3978 permit, including the date on which each permit will expire.

3979 (c) A list of the prescription drug wholesale distributors
 3980 ~~wholesalers~~, out-of-state prescription drug wholesale
 3981 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
 3982 distributors ~~wholesalers~~ permits that have been returned to the
 3983 department, were suspended, were revoked, have expired, or were
 3984 not renewed in the previous year.

3985 Section 34. Section 499.057, Florida Statutes, is amended
 3986 to read:

3987 499.057 Expenses and salaries.--All expenses and salaries
 3988 shall be paid out of the special fund hereby created in the
 3989 office of the Chief Financial Officer, which fund is to be known
 3990 as the "Florida Drug, Device, and Cosmetic Trust Fund."

3991 Section 35. Section 499.06, Florida Statutes, is amended to
 3992 read:

3993 499.06 Embargoing, detaining, or destroying article or
 3994 processing equipment which is in violation of law or rule.--

3995 (1) When a duly authorized agent of the department finds,
 3996 or has probable cause to believe, that any drug, device, or
 3997 cosmetic is in violation of any provision of this part ~~ss.~~
 3998 ~~499.001-499.081~~ or any rule adopted under such sections so as to
 3999 be dangerous, unwholesome, or fraudulent within the meaning of
 4000 this part ~~ss. 499.001-499.081~~, she or he may issue and enforce a
 4001 stop-sale, stop-use, removal, or hold order, which order gives
 4002 notice that such article or processing equipment is, or is
 4003 suspected of being, in violation and has been detained or
 4004 embargoed, and which order warns all persons not to remove, use,
 4005 or dispose of such article or processing equipment by sale or

PCB HCC 08-15

ORIGINAL

YEAR

4006 otherwise until permission for removal, use, or disposal is given
 4007 by such agent or the court. It is unlawful for any person to
 4008 remove, use, or dispose of such detained or embargoed article or
 4009 processing equipment by sale or otherwise without such
 4010 permission; and such act is a felony of the second degree,
 4011 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

4012 (2) When an article or processing equipment detained or
 4013 embargoed under subsection (1) has been found by such agent to be
 4014 in violation of law or rule, she or he shall, within 90 days
 4015 after the issuance of such notice, petition the circuit court, in
 4016 the jurisdiction of which the article or processing equipment is
 4017 detained or embargoed, for an order for condemnation of such
 4018 article or processing equipment. When such agent has found that
 4019 an article or processing equipment so detained or embargoed is
 4020 not in violation, she or he shall rescind the stop-sale, stop-
 4021 use, removal, or hold order.

4022 (3) If the court finds that the detained or embargoed
 4023 article or processing equipment is in violation, such article or
 4024 processing equipment shall, after entry of the court order, be
 4025 destroyed or made sanitary at the expense of the claimant
 4026 thereof, under the supervision of such agent; and all court
 4027 costs, fees, and storage and other proper expenses shall be taxed
 4028 against the claimant of such article or processing equipment or
 4029 her or his agent. However, when the violation can be corrected by
 4030 proper labeling of the article or sanitizing of the processing
 4031 equipment, and after such costs, fees, and expenses have been
 4032 paid and a good and sufficient bond, conditioned that such
 4033 article be so labeled or processed or such processing equipment
 4034 be so sanitized, has been executed, the court may by order direct

PCB HCC 08-15

ORIGINAL

YEAR

4035 | that such article or processing equipment be delivered to the
 4036 | claimant thereof for such labeling, processing, or sanitizing,
 4037 | under the supervision of an agent of the department. The expense
 4038 | of such supervision shall be paid by the claimant. Such bond
 4039 | shall be returned to the claimant of the article or processing
 4040 | equipment upon representation to the court by the department that
 4041 | the article or processing equipment is no longer in violation of
 4042 | this part ~~ss. 499.001-499.081~~ and that the expenses of such
 4043 | supervision have been paid.

4044 | (4) When the department or any of its authorized agents
 4045 | finds in any room, building, vehicle of transportation, or other
 4046 | structure any perishable articles that are unsound or contain any
 4047 | filthy, decomposed, or putrid substances, or which may be
 4048 | poisonous or deleterious to health or otherwise unsafe, the same
 4049 | being hereby declared to be a nuisance, the department, or its
 4050 | authorized agent, shall forthwith condemn or destroy such
 4051 | articles or in any other manner render such articles unsalable.

4052 | Section 36. Section 499.062, Florida Statutes, is amended,
 4053 | section 499.063, Florida Statutes, is renumbered as section (2)
 4054 | of that section and amended, and section 499.064, Florida
 4055 | Statutes, is renumbered as paragraphs (2)(a) and (b) of that
 4056 | section and amended, to read:

4057 | 499.062 ~~Cause for~~ Seizure and condemnation of drugs,
 4058 | devices, or cosmetics.--

4059 | (1) Any article of any drug, device, or cosmetic that is
 4060 | adulterated or misbranded under this part ~~ss. 499.001-499.081~~ is
 4061 | subject to seizure and condemnation by the department or by its
 4062 | duly authorized agents designated for that purpose in regard to
 4063 | drugs, devices, or cosmetics.

PCB HCC 08-15

ORIGINAL

YEAR

4064 (2) ~~499.063~~ ~~Seizure; procedure; prohibition on sale or~~
 4065 ~~disposal of article; penalty.~~ Whenever a duly authorized officer
 4066 or employee of the department finds cause, or has probable cause
 4067 to believe that cause exists, for the seizure of any drug,
 4068 device, or cosmetic, as set out in this part ~~ss. 499.001-499.081~~,
 4069 he or she shall affix to the article a tag, stamp, or other
 4070 appropriate marking, giving notice that the article is, or is
 4071 suspected of being, subject to seizure under this part ~~ss.~~
 4072 ~~499.001-499.081~~ and that the article has been detained and seized
 4073 by the department. Such officer or employee shall also warn all
 4074 persons not to remove or dispose of the article, by sale or
 4075 otherwise, until permission is given by the department or the
 4076 court. Any person who violates this subsection is guilty of a
 4077 felony of the second degree, punishable as provided in s.
 4078 775.082, s. 775.083, or s. 775.084.

4079 (a) ~~499.064~~ ~~Condemnation and sale; release of seized~~
 4080 ~~article.~~

4081 ~~(1)~~ When any article detained or seized under this
 4082 subsection ~~s. 499.063~~ has been found by the department to be
 4083 subject to seizure and condemnation ~~under s. 499.063~~, the
 4084 department shall petition the court for an order of condemnation
 4085 or sale, as the court directs. The proceeds of the sale of drugs,
 4086 devices, and cosmetics, less the legal costs and charges, shall
 4087 be deposited into the Florida Drug, Device, and Cosmetic Trust
 4088 Fund.

4089 (b) ~~(2)~~ If the department finds that any article seized
 4090 under this subsection ~~s. 499.063~~ was not subject to seizure, the
 4091 department or the designated officer or employee shall remove the
 4092 tag or marking.

PCB HCC 08-15

ORIGINAL

YEAR

4093 Section 37. Section 499.065, Florida Statutes, is amended
 4094 to read:

4095 499.065 Inspections; imminent danger.--

4096 (1) Notwithstanding s. 499.051, the department shall
 4097 inspect each prescription drug wholesale distributor
 4098 establishment, prescription drug repackager establishment,
 4099 veterinary prescription drug wholesale distributor establishment,
 4100 limited prescription drug veterinary wholesale distributor
 4101 ~~wholesaler~~ establishment, and retail pharmacy drug wholesale
 4102 distributor ~~wholesaler~~ establishment that is required to be
 4103 permitted under this part ~~chapter~~ as often as necessary to ensure
 4104 compliance with applicable laws and rules. The department shall
 4105 have the right of entry and access to these facilities at any
 4106 reasonable time.

4107 (2) To protect the public from prescription drugs that are
 4108 adulterated or otherwise unfit for human or animal consumption,
 4109 the department may examine, sample, seize, and stop the sale or
 4110 use of prescription drugs to determine the condition of those
 4111 drugs. The department may immediately seize and remove any
 4112 prescription drugs if the State Surgeon General or his or her
 4113 designee determines that the prescription drugs represent a
 4114 threat to the public health. The owner of any property seized
 4115 under this section may, within 10 days after the seizure, apply
 4116 to a court of competent jurisdiction for whatever relief is
 4117 appropriate. At any time after 10 days, the department may
 4118 destroy the drugs as contraband.

4119 (3) The department may determine that a prescription drug
 4120 wholesale distributor establishment, prescription drug repackager
 4121 establishment, veterinary prescription drug wholesale distributor

PCB HCC 08-15

ORIGINAL

YEAR

4122 establishment, limited prescription drug veterinary wholesale
 4123 distributor ~~wholesaler~~ establishment, or retail pharmacy drug
 4124 wholesale distributor ~~wholesaler~~ establishment that is required
 4125 to be permitted under this part ~~chapter~~ is an imminent danger to
 4126 the public health and shall require its immediate closure if the
 4127 establishment fails to comply with applicable laws and rules and,
 4128 because of the failure, presents an imminent threat to the
 4129 public's health, safety, or welfare. Any establishment so deemed
 4130 and closed shall remain closed until allowed by the department or
 4131 by judicial order to reopen.

4132 (4) For purposes of this section, a refusal to allow entry
 4133 to the department for inspection at reasonable times, or a
 4134 failure or refusal to provide the department with required
 4135 documentation for purposes of inspection, constitutes an imminent
 4136 danger to the public health.

4137 Section 38. Section 499.066, Florida Statutes, is amended
 4138 to read:

4139 499.066 Penalties; remedies.--In addition to other
 4140 penalties and other enforcement provisions:

4141 (1) The department may institute such suits or other legal
 4142 proceedings as are required to enforce any provision of this part
 4143 ~~ss. 499.001-499.081~~. If it appears that a person has violated any
 4144 provision of this part ~~ss. 499.001-499.081~~ for which criminal
 4145 prosecution is provided, the department may provide the
 4146 appropriate state attorney or other prosecuting agency having
 4147 jurisdiction with respect to such prosecution with the relevant
 4148 information in the department's possession.

4149 (2) If any person engaged in any activity covered by this
 4150 part ~~ss. 499.001-499.081~~ violates any provision of those

PCB HCC 08-15

ORIGINAL

YEAR

4151 sections, any rule adopted under those sections, or a cease and
 4152 desist order as provided by those sections, the department may
 4153 obtain an injunction in the circuit court of the county in which
 4154 the violation occurred or in which the person resides or has its
 4155 principal place of business, and may apply in that court for such
 4156 temporary and permanent orders as the department considers
 4157 necessary to restrain the person from engaging in any such
 4158 activities until the person complies with this part ~~ss. 499.001-~~
 4159 ~~499.081~~, the rules adopted under those sections, and the orders
 4160 of the department authorized by those sections or to mandate
 4161 compliance with this part ~~ss. 499.001-499.081~~, the rules adopted
 4162 under those sections, and any order or permit issued by the
 4163 department under those sections.

4164 (3) The department may impose an administrative fine, not
 4165 to exceed \$5,000 per violation per day, for the violation of any
 4166 provision of this part ~~ss. 499.001-499.081~~ or rules adopted under
 4167 those sections. Each day a violation continues constitutes a
 4168 separate violation, and each separate violation is subject to a
 4169 separate fine. All amounts collected pursuant to this section
 4170 shall be deposited into the Florida Drug, Device, and Cosmetic
 4171 Trust Fund and are appropriated for the use of the department in
 4172 administering this part ~~ss. 499.001-499.081~~. In determining the
 4173 amount of the fine to be levied for a violation, the department
 4174 shall consider:

- 4175 (a) The severity of the violation;
- 4176 (b) Any actions taken by the person to correct the
 4177 violation or to remedy complaints; and
- 4178 (c) Any previous violations.

PCB HCC 08-15

ORIGINAL

YEAR

4179 | (4) The department shall deposit any rewards, fines, or
 4180 | collections that are due the department and which derive from
 4181 | joint enforcement activities with other state and federal
 4182 | agencies which relate to this part ~~ss. 499.001-499.081~~, chapter
 4183 | 893, or the federal act, into the Florida Drug, Device, and
 4184 | Cosmetic Trust Fund. The proceeds of those rewards, fines, and
 4185 | collections are appropriated for the use of the department in
 4186 | administering this part ~~ss. 499.001-499.081~~.

4187 | (5) The department may issue an emergency order immediately
 4188 | suspending or revoking a permit if it determines that any
 4189 | condition in the establishment presents a danger to the public
 4190 | health, safety, and welfare.

4191 | (6) The department may issue an emergency order to
 4192 | immediately remove from commerce and public access any drug,
 4193 | device, or cosmetic, if the department determines that the drug,
 4194 | device, or cosmetic presents a clear and present danger to the
 4195 | public health, safety, and welfare.

4196 | (7) Resignation or termination of an affiliated party does
 4197 | not affect the department's jurisdiction or discretion to proceed
 4198 | with action to suspend or revoke a permit or to impose other
 4199 | penalties or enforcement actions authorized by law.

4200 | Section 39. Section 499.0661, Florida Statutes, is amended
 4201 | to read:

4202 | 499.0661 Cease and desist orders; removal of certain
 4203 | persons.--

4204 | (1) ~~(2)~~ CEASE AND DESIST ORDERS.--

4205 | (a) In addition to any authority otherwise provided in this
 4206 | chapter, the department may issue and serve a complaint stating
 4207 | charges upon any permittee or upon any affiliated party, whenever

PCB HCC 08-15

ORIGINAL

YEAR

4208 | the department has reasonable cause to believe that the person or
 4209 | individual named therein is engaging in or has engaged in conduct
 4210 | that is:

4211 | 1. An act that demonstrates a lack of fitness or
 4212 | trustworthiness to engage in the business authorized under the
 4213 | permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
 4214 | hazardous to the public health, or constitutes business
 4215 | operations that are a detriment to the public health;

4216 | 2. A violation of any provision of this part ~~ss. 499.001-~~
 4217 | ~~499.081~~;

4218 | 3. A violation of any rule of the department;

4219 | 4. A violation of any order of the department; or

4220 | 5. A breach of any written agreement with the department.

4221 | (b) The complaint must contain a statement of facts and
 4222 | notice of opportunity for a hearing pursuant to ss. 120.569 and
 4223 | 120.57.

4224 | (c) If a hearing is not requested within the time allowed
 4225 | by ss. 120.569 and 120.57, or if a hearing is held and the
 4226 | department finds that any of the charges are proven, the
 4227 | department may enter an order directing the permittee or the
 4228 | affiliated party named in the complaint to cease and desist from
 4229 | engaging in the conduct complained of and take corrective action
 4230 | to remedy the effects of past improper conduct and assure future
 4231 | compliance.

4232 | (d) A contested or default cease and desist order is
 4233 | effective when reduced to writing and served upon the permittee
 4234 | or affiliated party named therein. An uncontested cease and
 4235 | desist order is effective as agreed.

PCB HCC 08-15

ORIGINAL

YEAR

4236 (e) Whenever the department finds that conduct described in
 4237 paragraph (a) is likely to cause an immediate threat to the
 4238 public health, it may issue an emergency cease and desist order
 4239 requiring the permittee or any affiliated party to immediately
 4240 cease and desist from engaging in the conduct complained of and
 4241 to take corrective and remedial action. The emergency order is
 4242 effective immediately upon service of a copy of the order upon
 4243 the permittee or affiliated party named therein and remains
 4244 effective for 90 days. If the department begins nonemergency
 4245 cease and desist proceedings under this subsection, the emergency
 4246 order remains effective until the conclusion of the proceedings
 4247 under ss. 120.569 and 120.57.

4248 ~~(2)~~~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

4249 (a) The department may issue and serve a complaint stating
 4250 charges upon any affiliated party and upon the permittee involved
 4251 whenever the department has reason to believe that an affiliated
 4252 party is engaging in or has engaged in conduct that constitutes:

4253 1. An act that demonstrates a lack of fitness or
 4254 trustworthiness to engage in the business authorized under the
 4255 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
 4256 hazardous to the public health, or constitutes business
 4257 operations that are a detriment to the public health;

4258 2. A willful violation of this part ~~ss. 499.001-499.081~~;
 4259 however, if the violation constitutes a misdemeanor, a complaint
 4260 may not be served as provided in this section until the
 4261 affiliated party is notified in writing of the matter of the
 4262 violation and has been afforded a reasonable period of time, as
 4263 set forth in the notice, to correct the violation and has failed
 4264 to do so;

PCB HCC 08-15

ORIGINAL

YEAR

4265 | 3. A violation of any other law involving fraud or moral
 4266 | turpitude which constitutes a felony;
 4267 | 4. A willful violation of any rule of the department;
 4268 | 5. A willful violation of any order of the department; or
 4269 | 6. A material misrepresentation of fact, made knowingly and
 4270 | willfully or made with reckless disregard for the truth of the
 4271 | matter.
 4272 | (b) The complaint must contain a statement of facts and
 4273 | notice of opportunity for a hearing pursuant to ss. 120.569 and
 4274 | 120.57.
 4275 | (c) If a hearing is not requested within the time allotted
 4276 | by ss. 120.569 and 120.57, or if a hearing is held and the
 4277 | department finds that any of the charges in the complaint are
 4278 | proven true, the department may enter an order removing the
 4279 | affiliated party or restricting or prohibiting participation by
 4280 | the person in the affairs of that permittee or of any other
 4281 | permittee.
 4282 | (d) A contested or default order of removal, restriction,
 4283 | or prohibition is effective when reduced to writing and served on
 4284 | the permittee and the affiliated party. An uncontested order of
 4285 | removal, restriction, or prohibition is effective as agreed.
 4286 | (e)1. The chief executive officer, designated
 4287 | representative, or the person holding the equivalent office, of a
 4288 | permittee shall promptly notify the department if she or he has
 4289 | actual knowledge that any affiliated party is charged with a
 4290 | felony in a state or federal court.
 4291 | 2. Whenever any affiliated party is charged with a felony
 4292 | in a state or federal court or with the equivalent of a felony in
 4293 | the courts of any foreign country with which the United States

PCB HCC 08-15

ORIGINAL

YEAR

4294 maintains diplomatic relations, and the charge alleges violation
 4295 of any law involving prescription drugs, pharmaceuticals, fraud,
 4296 theft, or moral turpitude, the department may enter an emergency
 4297 order suspending the affiliated party or restricting or
 4298 prohibiting participation by the affiliated party in the affairs
 4299 of the particular permittee or of any other permittee upon
 4300 service of the order upon the permittee and the affiliated party
 4301 charged. The order must contain notice of opportunity for a
 4302 hearing pursuant to ss. 120.569 and 120.57, where the affiliated
 4303 party may request a postsuspension hearing to show that continued
 4304 service to or participation in the affairs of the permittee does
 4305 not pose a threat to the public health or the interests of the
 4306 permittee and does not threaten to impair public confidence in
 4307 the permittee. In accordance with applicable departmental rules,
 4308 the department shall notify the affiliated party whether the
 4309 order suspending or prohibiting the person from participation in
 4310 the affairs of a permittee will be rescinded or otherwise
 4311 modified. The emergency order remains in effect, unless otherwise
 4312 modified by the department, until the criminal charge is disposed
 4313 of. The acquittal of the person charged, or the final, unappealed
 4314 dismissal of all charges against the person, dissolves the
 4315 emergency order but does not prohibit the department from
 4316 instituting proceedings under paragraph (a). If the person
 4317 charged is convicted or pleads guilty or nolo contendere, whether
 4318 or not an adjudication of guilt is entered by the court, the
 4319 emergency order shall become final.

4320 (f) Any affiliated party removed pursuant to this section
 4321 is not eligible for reemployment by the permittee or to be an
 4322 affiliated party of any permittee except upon the written consent

PCB HCC 08-15

ORIGINAL

YEAR

4323 of the department. Any affiliated party who is removed,
 4324 restricted, or prohibited from participating in the affairs of a
 4325 permittee pursuant to this section may petition the department
 4326 for modification or termination of the removal, restriction, or
 4327 prohibition.

4328 Section 40. Section 499.067, Florida Statutes, is amended
 4329 to read:

4330 499.067 Denial, suspension, or revocation of permit,
 4331 certification, or registration.--

4332 (1)(a) The department may deny, suspend, or revoke a permit
 4333 if it finds that there has been a substantial failure to comply
 4334 with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501,
 4335 or chapter 893, the rules adopted under any of those sections or
 4336 chapters, any final order of the department, or applicable
 4337 federal laws or regulations or other state laws or rules
 4338 governing drugs, devices, or cosmetics.

4339 (b) The department may deny an application for a permit or
 4340 certification, or suspend or revoke a permit or certification, if
 4341 the department finds that:

4342 1. The applicant is not of good moral character or that it
 4343 would be a danger or not in the best interest of the public
 4344 health, safety, and welfare if the applicant were issued a permit
 4345 or certification.

4346 2. The applicant has not met the requirements for the
 4347 permit or certification.

4348 3. The applicant is not eligible for a permit or
 4349 certification for any of the reasons enumerated in s. 499.012
 4350 ~~499.01 or s. 499.012(5)~~.

PCB HCC 08-15

ORIGINAL

YEAR

4351 4. The applicant, permittee, or person certified under s.
 4352 499.012(16) ~~(11)~~ demonstrates any of the conditions enumerated in
 4353 s. 499.012 ~~499.01~~ or s. ~~499.012(5)~~.

4354 5. The applicant, permittee, or person certified under s.
 4355 499.012(16) ~~(11)~~ has committed any violation of ss. 499.005-
 4356 499.0054.

4357 (2) The department may deny, suspend, or revoke any
 4358 registration required by the provisions of this part ~~ss. 499.001-~~
 4359 ~~499.081~~ for the violation of any provision of this part ~~ss.~~
 4360 ~~499.001-499.081~~ or of any rules adopted under those sections.

4361 (3) The department may revoke or suspend a permit:

4362 (a) If the permit was obtained by misrepresentation or
 4363 fraud or through a mistake of the department;

4364 (b) If the permit was procured, or attempted to be
 4365 procured, for any other person by making or causing to be made
 4366 any false representation; or

4367 (c) If the permittee has violated any provision of this
 4368 part ~~ss. 499.001-499.081~~ or rules adopted under those sections.

4369 (4) If any permit issued under this part ~~ss. 499.001-~~
 4370 ~~499.081~~ is revoked or suspended, the owner, manager, operator, or
 4371 proprietor of the establishment shall cease to operate as the
 4372 permit authorized, from the effective date of the suspension or
 4373 revocation until the person is again registered with the
 4374 department and possesses the required permit. If a permit is
 4375 revoked or suspended, the owner, manager, or proprietor shall
 4376 remove all signs and symbols that identify the operation as
 4377 premises permitted as a drug wholesaling establishment; drug,
 4378 device, or cosmetic manufacturing establishment; or retail
 4379 establishment. The department shall determine the length of time

PCB HCC 08-15

ORIGINAL

YEAR

4380 for which the permit is to be suspended. If a permit is revoked,
 4381 the person that owns or operates the establishment may not apply
 4382 for any permit under this part ~~ss. 499.001-499.081~~ for a period
 4383 of 1 year after the date of the revocation. A revocation of a
 4384 permit may be permanent if the department considers that to be in
 4385 the best interest of the public health.

4386 (5) The department may deny, suspend, or revoke a permit
 4387 issued under this part ~~ss. 499.001-499.081~~ which authorizes the
 4388 permittee to purchase prescription drugs, if any owner, officer,
 4389 employee, or other person who participates in administering or
 4390 operating the establishment has been found guilty of any
 4391 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,
 4392 chapter 501, or chapter 893, any rules adopted under any of those
 4393 sections or chapters, or any federal or state drug law,
 4394 regardless of whether the person has been pardoned, had her or
 4395 his civil rights restored, or had adjudication withheld.

4396 (6) The department shall deny, suspend, or revoke the
 4397 permit of any person or establishment if the assignment, sale,
 4398 transfer, or lease of an establishment permitted under this part
 4399 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil
 4400 action, or criminal prosecution.

4401 (7) Notwithstanding s. 120.60(5), if a permittee fails to
 4402 comply with s. 499.012(6) ~~499.01(7)~~, the department may revoke
 4403 the permit of the permittee and shall provide notice of the
 4404 intended agency action by posting a notice at the department's
 4405 headquarters and by mailing a copy of the notice of intended
 4406 agency action by certified mail to the most recent mailing
 4407 address on record with the department and, if the permittee is

PCB HCC 08-15

ORIGINAL

YEAR

4408 | not a natural person, to the permittee's registered agent on file
4409 | with the Department of State.

4410 | Section 41. This act shall take effect July 1, 2008.