Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the FD&C Act.

On September 28, 2007, the U.S. District Court District of New Jersey entered judgment against Dr. Poet for 13 counts of mail fraud in violation of 18 U.S.C. 2 and 1341 and 1 count of causing a drug to be misbranded while it was held for sale after shipment in interstate commerce with the intent to defraud or mislead in violation of 21 U.S.C. 331(k), 333(a)(2), and 352(i)(3).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for those convictions is as follows: During 2003–2004, Dr. Poet was a physician licensed to practice medicine in the State of New Jersey. Dr. Poet owned and operated the Shore Laser Center and PEAU, both located in New Jersey. As part of his practice, Dr. Poet injected patients with BOTOX, a Botulinum Toxin Type A drug.

From on or about December 4, 2003, through in or about December 2004, Dr. Poet knowingly and willfully devised a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations, and promises. He maintained a Web site and placed regular advertisements in local newspapers offering BOTOX treatments at his office. Between December 4, 2003, and November 8, 2004, Dr. Poet placed 13 orders for a total of 26 vials of TRI–Toxin, a Botulinum Toxin Type A drug manufactured by Toxin Research International, Inc. TRI–Toxin was labeled "For Research Purposes Only, Not for Human Use." Dr. Poet injected many of the approximately 130 patients who sought BOTOX treatments with unapproved TRI–Toxin between January 1, 2004, and December 1, 2004. As part of his scheme to defraud, Dr. Poet did not inform most of his patients receiving the TRI–Toxin injections that they were receiving injections of a product not approved by FDA. Dr. Poet charged patients the same price for the cheaper, unapproved TRI–Toxin and the approved BOTOX. For purposes of executing the scheme and artifice, Dr. Poet knowingly and willfully caused the TRI–Toxin to be delivered by private and commercial interstate carrier.

As a result of his convictions, on December 13, 2010, FDA sent Dr. Poet a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Poet was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Dr. Poet an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Poet failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Albert Poet has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Poet is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see **DATES**) (see sections 306(c)(1)(B) and (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Poet, in any capacity during Dr. Poet's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Poet provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Poet during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Poet for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2010–N–0478 and sent to the Division of Dockets Management (*see* **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–4778 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–0264 (formerly 82N–0096), and FDA–1983–N–0137 (formerly 83N–0095); DESI 6514, 11935, and 12152]

Drugs for Human Use; Drug Efficacy Study Implementation; Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Withdrawal of Hearing Requests; Final Resolution of Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to oral prescription drugs offered for relief of symptoms of cough, cold, or allergy, Docket Nos. FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–0264 (formerly 82N–0096), and FDA–1983–N–0137 (formerly 83N–0095), have been withdrawn. Therefore, shipment in interstate commerce of the products identified in those dockets, or any identical, related, or similar (IRS) product that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) (other than an over-the-counter (OTC) product that complies with an

applicable OTC monograph), is unlawful as of the effective date of this notice.

DATES: *Effective Date:* This notice is effective March 3, 2011.

ADDRESSES: All communications in response to this notice should be identified with the appropriate docket number, and directed to Sakineh Walther, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, rm. 5242, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993–0002, 301–796–3349, e-mail: *sakineh.walther@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of January 7, 2011 (76 FR 1174) (the January 7, 2011, notice), FDA announced that all outstanding hearing requests pertaining to certain dockets established under the Agency's Drug Efficacy Study Implementation (DESI) program had been withdrawn.[1] [2] Also in that notice, FDA announced the withdrawal of certain hearing requests pertaining to Docket Nos. FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–0264 (formerly 82N–0096), and FDA–1983–N–0137 (formerly 83N–0095), and offered an opportunity for companies with outstanding hearing requests under those dockets to withdraw or affirm their outstanding hearing requests.

A. Docket No. FDA–1981–N–0077 (formerly 81N–0393) (DESI 6514)

The products reviewed under Docket No. *FDA–1981–N–0077 (formerly 81N–0393)* (DESI 6514) were Phenergan Expectorant with Codeine (containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and codeine phosphate, marketed under NDA 8–306); Phenergan VC Expectorant Plain (containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and phenylephrine hydrochloride, marketed under NDA 8–306); Phenergan VC Expectorant With Codeine (containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, phenylephrine hydrochloride, and codeine phosphate, marketed under NDA 8–306); Phenergan Expectorant Plain (containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, and sodium citrate, marketed under NDA 8–604); and Pediatric Phenergan Expectorant with Dextromethorphan (containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and dextromethorphan hydrobromide, marketed under NDA 11–265). In a notice published in the **Federal Register** of May 25, 1982 (47 FR 22610), FDA revoked the temporary exemption that permitted these drug products, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness, and offered an opportunity for a hearing on a proposal to withdraw approval of the NDAs for the products.

After Wyeth Laboratories, the holder of the NDAs for the Phenergan products, withdrew its hearing request after approval of reformulated versions of four of its five products, FDA announced in the **Federal Register** of August 15, 1984 (49 FR 32681) that the Agency was withdrawing approval of NDAs 8–306, 8–604, and 11–265 pertaining to the old formulations of the Phenergan products, effective September 14, 1984.

At the time of the January 7, 2011, notice (76 FR 1174), there were two outstanding hearing requests under this docket filed by Bay Laboratories, 3654 West Jarvis, Skokie, IL 60076, for its IRS products Promethazine Expectorant with Codeine, Promethazine VC Expectorant Plain, Promethazine VC Expectorant with Codeine, Promethazine Expectorant Plain, and Promethazine Pediatric Expectorant, and by National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to all five Phenergan products considered under this docket. FDA was unable to find current contact information for Bay Laboratories and National Pharmaceuticals. In the January 7, 2011, notice, FDA gave these companies an opportunity to affirm or withdraw their hearing requests. Requests that were not affirmed within 30 days of that notice were to be deemed withdrawn by FDA.

B. Docket FDA–1981–N–0248 (formerly 81N–0396) (DESI 6514)

The products reviewed under Docket No. FDA–1981–N–0248 (formerly 81N–0396) (DESI 6514) were Dimetane Expectorant (containing brompheniramine maleate, phenylephrine hydrochloride, phenylpropanolamine hydrochloride, and guaifenesin, marketed under NDA 11–694); Dimetane Expectorant-DC (containing codeine phosphate, brompheniramine maleate, phenylephrine hydrochloride, phenylpropanolamine hydrochloride, and guaifenesin, marketed under NDA 11–694); and Actifed-C Expectorant (containing codeine phosphate, triprolidine hydrochloride, pseudoephedrine hydrochloride, and guaifenesin, marketed under NDA 12–575). In a notice published in the **Federal Register** of May 25, 1982, FDA revoked the temporary exemption that permitted these drug products, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness, and offered an opportunity for a hearing on a proposal to withdraw approval of the NDAs for the products.

On April 3, 1984, A.H. Robins, the holder of the NDA for Dimetane Expectorant and Dimetane Expectorant-DC, withdrew its hearing request after approval of reformulated versions of its products. Accordingly, in the **Federal Register** of August 24, 1984 (49 FR 33726), FDA announced that it was withdrawing approval of those portions of NDA 11–694 pertaining to the old formulations of the Dimetane Expectorant products, effective September 24, 1984.

In the **Federal Register** of September 14, 1984 (49 FR 36169), FDA announced that it was withdrawing approval of those portions of NDA 12–575 pertaining to the old formulation of Actifed-C Expectorant, effective October 15, 1984, after the NDA holder, Burroughs Wellcome, obtained approval for a reformulated version of the product and withdrew its hearing request.

At the time of the January 7, 2011, notice, there were two outstanding

[1] For background on the DESI review in general and the DESI review as it relates to the dockets addressed in this notice, please see the January 7, 2011, notice.

[2] In the January 7, 2011, notice, FDA stated that with respect to Docket No. FDA–1982–N–0225 (formerly 82N–0078), Chlor-Trimeton Repetabs Tablets, containing 12 milligrams (mg) chlorpheniramine maleate and marketed under NDA 7–638, had been discontinued. FDA notes that NDA 7–638 is currently active; however, products under it are not marketed for indications found ineffective under DESI.

hearing requests under this docket filed by Bay Laboratories, 3654 West Jarvis, Skokie, IL 60076, for its IRS products Triphen Expectorant, Triphen Expectorant DC, and Pseudodine "C" Expectorant, and by National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to Dimetane Expectorant, Dimetane Expectorant DC, and Actifed-C. FDA was unable to find current contact information for Bay Laboratories and National Pharmaceuticals. In the January 7, 2011, notice, FDA gave these companies an opportunity to affirm or withdraw their hearing requests. Requests that were not affirmed within 30 days of that notice were to be deemed withdrawn by FDA.

C. Docket FDA–1982–N–0046 (formerly 82N–0095) (DESI 6514, 11935)

The products reviewed under Docket No. FDA–1982–N–0046 (formerly 82N–0095) (DESI 6514 and 11935) were Ambenyl Expectorant (containing codeine sulfate, bromodiphenhydramine hydrochloride, diphenhydramine hydrochloride, ammonium chloride, potassium guaiacolsulfonate, and menthol, marketed under NDA 9–319); and Pyribenzamine and Ephedrine Tablets (containing tripelennamine hydrochloride and 12 mg ephedrine sulfate, marketed under NDA 5–914). In a notice published in the **Federal Register** of May 25, 1982 (47 FR 22604), FDA revoked the temporary exemption that permitted these drug products, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness, and offered an opportunity for a hearing on a proposal to withdraw approval of the NDAs for the products.

In the **Federal Register** of May 24, 1983 (48 FR 23311), FDA announced that it was withdrawing approval of NDA 5–914 as it pertains to Pyribenzamine and Ephedrine Tablets, effective June 23, 1983, because no hearing was requested for the product by the NDA holder. On February 27, 1984, Marion Laboratories, the NDA holder for Ambenyl Expectorant, withdrew its hearing request after a reformulated version of its product was approved. Accordingly, in the **Federal Register** of August 24, 1984, FDA announced it was withdrawing approval of those portions of NDA 9–319 pertaining to the old formulation of Ambenyl Expectorant, effective September 24, 1984.

At the time of the January 7, 2011, notice, there was one outstanding hearing request under this docket filed by National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to Ambenyl Expectorant. FDA was unable to find current contact information for National Pharmaceuticals. In the January 7, 2011, notice, FDA gave this company an opportunity to affirm or withdraw its hearing request. Its hearing request was to be deemed withdrawn if the company did not affirm the request within 30 days of that notice.

D. Docket FDA–1982–N–0264 (formerly 82N–0096) (DESI 12152)

The product reviewed under Docket No. FDA–1982–N–0264 (formerly 82N–0096) (DESI 12152) was Ornade Spansules. Ornade Spansules, as formulated early in the DESI review process, was a three-ingredient product containing 8 mg of chlorpheniramine maleate, 50 mg of phenylpropanolamine hydrochloride, and 2.5 mg of isopropamide, and was marketed under NDA 12–152. Subsequently, Ornade Spansules was reformulated as a controlled-release product containing 12 mg chlorpheniramine maleate and 75 mg phenylpropanolamine. In a notice published in the **Federal Register** of August 17, 1982 (47 FR 35870), FDA revoked the temporary exemption that permitted Ornade Spansules, as originally formulated, and those products IRS to it, to remain on the market beyond the time limit established for DESI. In the notice, FDA also announced the conditions for marketing Ornade Spansules, as reformulated, and the products IRS to it, for the indication for which they were regarded as effective, and offered an opportunity for a hearing concerning a proposal to withdraw approval of the NDA with respect to the old formulation and the indications reclassified to lacking substantial evidence of effectiveness.

In the **Federal Register** of December 12, 1984 (49 FR 48387), FDA announced that it was withdrawing approval of those portions of NDA 12–152 covering the old, three-ingredient formulation for Ornade Spansules, effective January 11, 1985, noting that no party submitted a hearing request regarding the three-ingredient formulation.

At the time of the January 7, 2011, notice, there were two outstanding hearing requests under this docket filed by Pioneer Pharmaceuticals, Inc., 209 40th Street, Irvington, NJ 07111, for its IRS product characterized by the company as a generic version of Ornade Spansules, and by Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647, for its IRS product, a sustained release product containing chlorpheniramine and phenylpropanolamine. FDA did not receive any response to its attempt to contact Zenith Laboratories and was unable to find current contact information for Pioneer Pharmaceuticals, Inc. In the January 7, 2011, notice, FDA gave these companies an opportunity to affirm or withdraw their hearing requests. Requests that were not affirmed within 30 days of that notice were to be deemed withdrawn by FDA.

E. Docket FDA–1983–N–0137 (formerly 83N–0095) (DESI 11935)

The products reviewed under Docket No. FDA–1983–N–0137 (formerly 83N–0095) (DESI 11935) were Dimetapp Extentabs and Dimetapp Elixir. As originally formulated during the period of the DESI review, Dimetapp Extentabs contained 12 mg brompheniramine maleate, 15 mg phenylephrine hydrochloride, and 15 mg phenylpropanolamine hydrochloride in controlled-release form, and was marketed under NDA 12–436; and Dimetapp Elixir contained 4 mg brompheniramine maleate, 5 mg phenylephrine hydrochloride, and 5 mg phenylpropanolamine hydrochloride per 5 milliliters (mL), and was marketed under NDA 13–087. In a notice published in the **Federal Register** of December 23, 1983 (48 FR 56854) (the December 23, 1983, notice), FDA revoked the temporary exemption that permitted these drug products, and those products IRS to these products, to remain on the market beyond the time limit established for DESI, and offered an opportunity for a hearing concerning a proposal to withdraw approval of the NDAs for the original formulations of these products and for the indications reclassified to lacking substantial evidence of effectiveness.

At the time of the publication of the December 23, 1983, notice, the manufacturer had submitted supplemental applications proposing to reformulate Dimetapp Extentabs to contain 12 mg brompheniramine maleate and 75 mg phenylpropanolamine hydrochloride in a controlled-release form, and Dimetapp Elixir to contain 4 mg brompheniramine maleate and 25 mg phenylpropanolamine hydrochloride per 5 mL. The supplements to NDA 12–436 and NDA 13–087 were approved by FDA on April 20, 1984, and March 29, 1984, respectively. In the December 23, 1983, notice, FDA also announced the conditions for marketing the reformulated versions of these products

for the indication for which they were regarded as effective.

At the time of the January 7, 2011, notice (76 FR 1174), there were 14 outstanding hearing requests under this docket filed by American Therapeutics Inc., 75 Carlough Rd., Bohemia, NY 11716, for its product IRS to Dimetapp Extentab Tablets; Amide Pharmaceutical, Inc., 101 East Main St., Little Falls, NJ 07424, for its IRS product Ami-Tapp; Bay Laboratories, Inc., 3654 West Jarvis, Skokie, IL 60076, for Triphen Elixir, its product IRS to Dimetapp Elixir; Carnrick Laboratories, Inc., 65 Horse Hill Rd., Cedar Knolls, NJ 07927, for Nolamine Timed Release Tablets, its product IRS to Dimetapp Extentabs; Copley Pharmaceutical, Inc., 398 West Second St., P.O. Box 107, Boston, MA 02127, for its products IRS to Dimetapp Extentabs; LuChem Pharmaceuticals, Inc., P.O. Box 6038, 8910 Linwood Ave., Shreveport, LA 71136, for its IRS products Ban-Tuss HC, Ban-Tuss C Expectorant, Tuss-Delay Tablets, Ban-Tuss Plain, Klerist-D Tablets, Respergen, Am-Tuss Liquid, Novadyne DH, Novadyne Expectorant, Dexophed Tablets, Chem-Tuss-SR, Chem-Tuss Elixir, Chem-Tuss DM, Chem-Tuss DME, and Chem-Tuss N; Mayrand Inc., 4 Dundas Circle, P.O. Box 8860, Greensboro, NC 27419, for its products IRS to Dimetapp Extentabs and Dimetapp Elixir; National Pharmaceutical Manufacturing Co., 7205 Windsor Blvd., Baltimore, MD 21207, for its product IRS to Dimetapp Elixir; Pharmaceutical Basics, Inc., 301 S. Cherokee, Denver, CO 80223, for its IRS product Basamine S.R. Tablets; Pioneer Pharmaceuticals, Inc., 209 40th St., Irvington, NJ 07111, for Pioten Tablets, its product IRS to Dimetapp Extentabs; Quantum Pharmics, Ltd., 26 Edison St., Amityville, NY 11701, for its IRS product, Brom-Tapp; Superpharm Corp., 155 Oval Dr., Central Islip, NY 11722, for its product IRS to Dimetapp Extentab Tablets; United States Trading Corp., 10718 McCune Ave., Los Angeles, CA 90034, for its products IRS to Dimetapp Extentabs; and Upsher-Smith Laboratories, Inc., 14905 23d Ave. North, Minneapolis, MN 55441, for unspecified products.

FDA was unable to find current contact information for American Therapeutics, Amide Pharmaceutical, Inc., Bay Laboratories, Inc., National Pharmaceutical Manufacturing Co., Pharmaceutical Basics, Inc., Superpharm Corp., and United States Trading Corp. FDA did not receive any response to its attempt to contact Carnrick Laboratories, a subsidiary of Elan Corp., PLC, 800 Gateway Blvd., South San Francisco, CA 94080; Copley Pharmaceutical, Inc.; LuChem Pharmaceuticals, Inc.; Merz Pharmaceuticals, LLC, P.O. Box 18806, Greensboro, NC 27419, successor to Mayrand Inc. Pharmaceuticals; Pioneer Pharmaceuticals, Inc.; Quantum Pharmics, Ltd.; or Upsher-Smith Laboratories, Inc. In the January 7, 2011, notice, FDA gave these companies an opportunity to affirm or withdraw their hearing requests. Requests that were not affirmed within 30 days of that notice were to be deemed withdrawn by FDA.

II. Final Resolution of Docket Nos. FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–264 (formerly 82N–0096), and FDA–1983–N–0137 (formerly 83N–0095)

The time period for responding to the January 7, 2011, notice has elapsed, and no companies with outstanding hearing requests responded to the notice. Because no outstanding hearing requests were affirmed in response to the January 7, 2011, notice (or in response to FDA's previous attempts to contact companies with outstanding hearing requests), all of the outstanding hearing requests pertaining to Docket Nos. FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–0264 (formerly 82N–0096), and FDA–1983–N–0137 (formerly 83N–0095) are deemed to be withdrawn. Therefore, shipment in interstate commerce of the products identified in those dockets, or any IRS product that is not the subject of an approved NDA or ANDA, is unlawful as of the effective date of this notice. This notice is not applicable to OTC products that comply with an OTC monograph (21 CFR 310.6(f)). Any person who wishes to determine whether a specific product is covered by this notice should write to the Center for Drug Evaluation and Research (*see* **ADDRESSES**).

III. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the Agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent to Sakineh Walther (*see* **ADDRESSES**).

Firms should also update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products. FDA plans to rely on its existing records, including drug listing records or other available information, when it targets violations for enforcement action. Firms should be aware that, after the effective date of this notice, FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice that is not the subject of an ongoing DESI proceeding.

IV. Reformulated Products

Some of the active ingredients found in drug products covered by this notice are included in the OTC monograph in 21 CFR part 341, "Cold, Cough, Allergy, Bronchodilator, and Antihistamine Drug Products for Over-the-Counter Human Use." OTC products that comply with the monograph may be marketed without approval.

However, FDA cautions firms against reformulating products into OTC products or different unapproved new drugs that are marketed under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combination of active ingredients have the potential to confuse health care practitioners and harm patients.

This notice is issued under sections 502 and 505 of the FD&C Act (21 U.S.C. 352 and 355), and under authority delegated to the Assistant Commissioner for Policy under section 1410.21 of the FDA Staff Manual Guide.

Dated: February 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4702 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P