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Dated: January 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-1981-N-0361 (formerly 81N-0391), FDA-1981-N-0077 (formerly 81N-0393), FDA-1981-N-0248 (formerly 81N-0396), FDA-1982-N-0225 (formerly 82N-0078), FDA-1982-N-0046 (formerly 82N-0095), FDA-1982-N-0264 (formerly 82N-0096), FDA-1982-N-0310 (formerly 82N-0311), and FDA-1983-N-0137 (formerly 83N-0095); DESI 5213, 6290, 6303, 6514, 8658, 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; Opportunity To Affirm Outstanding Hearing Requests; Final Resolution of Dockets

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to Docket Nos. 81N-0391, 82N-0078, and 82N-0311 have been withdrawn and therefore, shipment in interstate commerce of the products identified in those dockets, or any identical, related, or similar product that is not the subject of an approved new drug application (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. FDA is also offering an opportunity to affirm outstanding hearing requests in Docket Nos. 81N-0393, 81N-0396, 82N-0095, 82N-0096, and 83N-0095. FDA will assume that companies with outstanding hearing requests that do not respond to this notice are no longer

interested in pursuing their requests, and will deem the requests withdrawn.

DATES: Effective Date: This notice is effective February 7, 2011. Hearing requests must be affirmed by notifying FDA by February 7, 2011. Hearing requests not affirmed within that time frame will be deemed withdrawn.

ADDRESSES: All communications in response to this notice should be identified with the appropriate docket number, and directed to the appropriate office listed as follows:

To affirm or withdraw hearing requests: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002.

All other communications: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT:

Sakineh Walther, 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

When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (FD&C act) required that “new drugs” be approved for safety by FDA before they could legally be sold in interstate commerce.¹ To this end, the FD&C Act made it the sponsor’s responsibility, prior to marketing a new drug, to submit a new drug application (NDA) to FDA to prove that its drug was safe. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS)² to the approved drug to be “covered” by that approval, and allowed those IRS

¹ A “new drug” is defined by the FD&C Act as a drug that “is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a ‘new drug’ if at any time prior to the enactment of this FD&C Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use * * *.” (21 U.S.C. 321(p)).

² Section 310.6(b)(1) (21 CFR 310.6(b)(1)) provides: “An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties.”

drugs to be marketed without independent approval.

In 1962, Congress amended the act to require that new drugs be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval. This amendment also necessitated that FDA conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The agency reviewed and re-evaluated the reports and published its findings in **Federal Register** notices. FDA’s administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

In the early 1970s, FDA granted temporary exemptions³ from the time limits established⁴ for completing certain phases of the DESI program for certain oral prescription drugs offered for relief of cough, cold, allergy, and related symptoms. The exemptions were granted because of the close relationship between these prescription drugs and drugs sold over the counter (OTC) that were subject to the ongoing OTC drug review (see 21 CFR part 330). Postponement of final evaluations of these DESI prescription products enabled the agency to consider the recommendations of the OTC review panel in addition to any evidence submitted by NDA holders and other parties in response to various DESI notices covering relevant products.

All drugs covered by the DESI review are “new drugs” under the FD&C Act. If FDA’s final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs. If FDA’s final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for such indications, provided

³ 38 FR 34481 (December 14, 1973).

⁴ 38 FR 4006 (February 9, 1973) and 37 FR 15022 (July 27, 1972).

it is the subject of an application approved for safety and effectiveness. Sponsors of drug products that have been found to be effective for one or more indications through the DESI process may rely on FDA's effectiveness determinations, but typically must update their labeling to conform to the indications found to be effective by FDA and to include any additional safety information required by FDA. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications if found to be effective under DESI; IRS drug products require an approved NDA or abbreviated new drug application (ANDA), as appropriate. Furthermore, labeling for drug products classified as effective may contain only those indications for which the review found the product effective unless the firm marketing the product has received an approval for the additional indication(s).

II. DESI Review of Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy

A. DESI Cough, Cold, or Allergy Dockets for Which Hearing Requests Have Been Withdrawn

1. Tussionex Tablets and Suspension and Omni-Tuss Suspension, Docket 81N-0391 (DESI 6514)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22606), FDA revoked the temporary exemption that permitted the drug products described below, 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.

Tussionex Tablets and Suspension, both containing dihydrocodeinone and phenyltoloxamine dihydrogen sulfate, were marketed under NDA 10-768, and labeled as antitussives. Omni-Tuss Suspension, containing codeine sulfate, phenyltoloxamine dihydrogen sulfate, chlorpheniramine maleate, ephedrine sulfate, and guaicol carbonate, was marketed under NDA 12-666, and was also labeled as an antitussive.

In response to the May 25, 1982, notice, timely hearing requests were filed by Pennwalt Corp., 755 Jefferson Rd., Rochester, NY 14623, for its products marketed under NDA 10-768⁵,

and Boots Pharmaceuticals, Inc., 6540 Line Ave., Shreveport, LA 71106-9989, for its product IRS to Omni-Tuss suspension.

Pennwalt, the NDA holder for Omni-Tuss Suspension, did not request a hearing for that product. On May 24, 1983 (48 FR 23311), FDA announced that it was withdrawing approval of NDA 12-666, effective June 23, 1983. On February 29, 1988, Pennwalt withdrew its hearing request for the Tussionex products, following approval of a reformulation of the suspension product (NDA 19-111). On March 23, 1988 (53 FR 9492), FDA announced it was withdrawing approval of NDA 10-768, effective April 22, 1988. On May 23, 1988, Boots withdrew its hearing request.

Thus, all outstanding hearing requests related to Docket 81N-0391 have now been withdrawn and, as stated previously, the approvals for NDA 10-768 and NDA 12-666 were withdrawn in 1988 and 1983, respectively. Shipment in interstate commerce of the previously mentioned products, 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 (address given previously).

2. Hycodan Syrup, Tablets, and Powder; Benadryl With Ephedrine Sulfate Kapseal; Chlor-Trimeton Repetabs Tablets; PBZ Lontabs and PBZ-SR; Dimetane Extentabs; Hispril Spansule Capsules; Disophrol Tablets; and Novrad with A.S.A. Pulvules; Docket 82N-0078 (DESI 5213, 6290, 6303, 8658, 11935)

In a notice published in the **Federal Register** on June 1, 1982 (47 FR 23809), FDA revoked the temporary exemption that permitted the drug products described below, 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 for certain indications, and offered an

contained in the hearing requests. In some cases, the companies requesting hearings identified the product that was the subject of the hearing request by name. In other cases, the company simply identified the subject of its hearing request as a product that is IRS to one of the products reviewed under DESI. In yet other cases, there is no information provided by the requester about the product that is the subject of its hearing request.

opportunity for a hearing on a proposal to withdraw approval of the NDAs for those indications.

Hycodan Syrup, Tablets, and Powder, containing hydrocodone bitartrate and homatropine methylbromide, were marketed under NDA 5-213. Benadryl with Ephedrine Sulfate Kapseal, containing diphenhydramine hydrochloride and ephedrine sulfate, was marketed under NDA 5-845. Chlor-Trimeton Repetabs Tablets, containing 12 milligrams (mg) chlorpheniramine maleate, were marketed under NDA 7-638. PBZ Lontabs and PBZ-SR, containing tripeleminamine hydrochloride, were marketed under NDA 10-533. Dimetane Extentabs, containing brompheniramine maleate, was marketed under NDA 10-799. Hispril Spansule Capsules, containing diphenylpyraline hydrochloride, was marketed under NDA 11-945. Disophrol Tablets, containing dexbrompheniramine maleate and pseudoephedrine sulfate, was marketed under NDA 12-394. Novrad with A.S.A. Pulvules, containing levopropoxyphene napsylate and aspirin, was marketed under NDA 13-097.

In response to the June 1, 1982, notice, timely hearing requests were filed by Cord Laboratories, Inc., 2555 W. Midway Blvd., Broomfield, CO 80020, for its IRS products Chlorpheniramine Maleate S.R. Capsules and Efedra-PA Tablets, and KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144, for its IRS products chlorpheniramine maleate sustained release capsules, 8 and 12 mg. A late hearing request was filed by Sidmak Laboratories, 17 West St., P.O. Box 371, East Hanover, NJ 07936, for three IRS products: Chlorpheniramine maleate 8 mg.; chlorpheniramine maleate 12 mg.; and a dexbrompheniramine maleate and pseudoephedrine sulfate product.

NDAs 5-213, 5-845, and 7-638 have not been withdrawn, but the products marketed under NDA 5-213 and NDA 7-638 have been discontinued, and the oral Benadryl products associated with NDA 5-845 are marketed with indications that are consistent with the OTC monograph, 21 CFR part 341. NDAs 10-533, 10-799, 11-945, and 12-394 were voluntarily withdrawn on November 7, 2007 (72 FR 62858), June 16, 2006 (71 FR 34940), March 21, 1994 (59 FR 9989), and October 9, 1986 (51 FR 36295), effective on December 7, 2007, June 16, 2006, April 1, 1994, and November 10, 1986, respectively. On June 7, 1977, FDA announced that it was withdrawing approval of NDA 13-097, effective June 13, 1977, for failure to file required reports (42 FR 29104). NDA 13-097 was included in

⁵ This **Federal Register** notice identifies the products that are the subjects of hearing requests to the extent possible based on the information

the June 1982 notice to inform manufacturers of IRS products of the agency's finding of effectiveness for the product (42 FR 23809).

On October 21, 2009, the hearing request filed by Cord Laboratories, Inc., was withdrawn by its successor-in-interest, Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020. On December 4, 2009, KV Pharmaceutical Co. also withdrew its hearing request. On February 15, 2010, Sidmak Laboratories' hearing request was withdrawn by its successor-in-interest, Teva Pharmaceuticals. Thus, all outstanding hearing requests related to Docket 82N-0078 have now been withdrawn.

Shipment in interstate commerce of the previously mentioned products, 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 (address given previously).

3. Actifed Syrup and Tablets; Docket 82N-0311 (DESI 11935)

In a notice published in the **Federal Register** on October 22, 1982 (47 FR 47085), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. In the notice, FDA also announced the conditions for marketing these products 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 NDAs for the indications reclassified to lacking substantial evidence of effectiveness.

Actifed Syrup and Tablets both contained triprolidine hydrochloride and pseudoephedrine hydrochloride, and were marketed under NDA 11-935 and NDA 11-936, respectively.

In response to the October 22, 1982, notice, timely hearing requests were filed by Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, for its IRS products Corphed Syrup and Tablets, and Lemmon Co., 850 Cathill Rd., Sellersville, PA 18960, for its IRS products Tri-Fed and Actiprem. A late hearing request was filed by Sidmak Laboratories, Inc., 17 West St., P.O. Box 371, East Hanover, NJ 07936, for its product IRS to Actifed Tablets.

On May 26, 1983, Lemmon Co. withdrew its hearing request relating to this docket. Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, the successor-in-interest to Cord Laboratories, Inc., withdrew its hearing request on October 21, 2009. On February 15, 2010, Teva Pharmaceuticals, the successor-in-interest to Sidmak Laboratories, withdrew its hearing request. Thus, all outstanding hearing requests related to Docket 82N-0311 have now been withdrawn. NDAs 11-935 and 11-936 were withdrawn by FDA on November 28, 1997, effective December 29, 1997, following requests by the application holders. (62 FR 63347).

Shipment in interstate commerce of the previously mentioned products, 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 (address given above).

B. *DESI Cough, Cold, or Allergy Dockets With Outstanding Hearing Requests*

In 2006, FDA announced a new drug safety initiative to address unapproved drugs currently being marketed in the United States, and to facilitate a rational process to bring all such unapproved drugs into the approval process. As part of the Unapproved Drugs Initiative, the Office of Compliance of the Center for Drug Evaluation and Research is reviewing proceedings that remain open under DESI. According to FDA's records, the dockets discussed below contain pending hearing requests. In cases where FDA was able to obtain current contact information for a company (or its successor-in-interest) or its representative, FDA sent letters directly to the companies (or their successors-in-interest) and/or their representatives requesting that outstanding hearing requests be withdrawn or affirmed within a specified time frame. In some cases, however, FDA was unable to find current contact information for the companies that requested hearings. Because many of the products that are the subjects of these hearing requests may no longer be marketed⁶ and some

⁶ For example, many of the products covered by these dockets, as originally formulated or as reformulated, contain phenylpropanolamine (PPA). In 2001, FDA proposed to withdraw several new drug applications for products containing PPA, due to evidence that the ingredient increases the risk of

of the companies that requested hearings may no longer be in business, FDA is seeking to determine whether there is continued interest in pursuing these outstanding hearing requests.

Through this **Federal Register** notice, FDA seeks to have any company with an outstanding hearing request covered by this notice that has not already responded to a direct communication from FDA either withdraw or affirm its hearing request. FDA will assume that companies with outstanding hearing requests that do not respond to this notice are no longer in business and/or do not have a continuing interest in the hearings, and FDA will deem their requests withdrawn.

To withdraw an outstanding hearing request, a company (or its successor-in-interest) or its representative should send a letter stating its intention to do so to the address provided above. The letter should include the docket number of the proceeding, as well as the name and NDC (National Drug Code) number of the product that is the subject of the hearing request.

To affirm an outstanding hearing request, a company (or its successor-in-interest), or its representative should send a letter stating its intention to do so to the address provided previously. The letter should include the docket number of the proceeding, as well as the name and NDC number of the product that is the subject of the hearing request. Letters affirming outstanding hearing requests must be postmarked or e-mailed within 30 calendar days of the date of this notice. Only currently outstanding hearing requests may be affirmed; this notice does not provide a new opportunity to request a hearing under any of these dockets.

1. Phenergan Expectorant With Codeine, Phenergan VC Expectorant Plain, Phenergan VC Expectorant With Codeine, Phenergan Expectorant Plain, and Pediatric Phenergan Expectorant With Dextromethorphan; Docket 81N-0393 (DESI 6514)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22610), FDA revoked the temporary exemption that permitted the drug products described below, 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

hemorrhagic stroke (66 FR 42665, August 14, 2001). FDA believes products containing PPA are no longer being marketed.

on a proposal to withdraw approval of the NDAs for the products.

Phenergan Expectorant With Codeine, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and codeine phosphate, was marketed under NDA 8-306. Phenergan VC Expectorant Plain, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and phenylephrine hydrochloride, was 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, was marketed under NDA 8-306. Phenergan Expectorant Plain, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, and sodium citrate, was marketed under NDA 8-604. Pediatric Phenergan Expectorant With Dextromethorphan, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and dextromethorphan hydrobromide, was marketed under NDA 11-265. All of the products were marketed as expectorants.

In response to the May 25, 1982, notice, timely hearing requests were 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; Cord Laboratories, Inc., 2555 W. Midway Blvd., Broomfield, CO 80020, for two IRS products, the first a syrup containing codeine phosphate, promethazine hydrochloride, potassium guaiacolsulfonate, citric acid, anhydrous, sodium citrate, hydrous, and ipecac fluidextract and the second a syrup containing codeine phosphate, promethazine hydrochloride, phenylephrine hydrochloride, potassium guaiacolsulfonate, citric acid, anhydrous, sodium citrate, hydrous, and ipecac fluidextract; Lederle Laboratories, 401 N Middletown Rd., Pearl River, NY 10965, for its products IRS to the Phenergan products considered under this docket except for the pediatric formulation; National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to all five Phenergan products considered under this docket; Purepac Pharmaceutical Co., 200 Elmora

Ave., Elizabeth, NJ 07207, for IRS products Promethazine HCl Expectorant VC with Codeine, Promethazine HCl Expectorant Plain, and Promethazine HCl Expectorant with Codeine; and Wyeth Laboratories, P.O. Box 8299, Philadelphia, PA 19101, the manufacturer of the Phenergan products, for all five of the Phenergan products considered under this docket.

On July 13, 1984, Wyeth, the holder of the NDAs for the Phenergan products, withdrew its hearing request after approval of reformulated versions of four of its five products. Accordingly, on August 15, 1984 (49 FR 32681), FDA announced that it 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. On October 25, 1984, Cord also withdrew its hearing request relating to this docket, based on discontinuation of the products that were the subject of the hearing request.

FDA sent letters to Pfizer, Inc., 235 East 42nd St., New York, NY 10017, successor to Lederle Laboratories, and to Actavis, 60 Columbia Rd., Building B, Morristown, NJ 07960, successor to Purepac Pharmaceuticals, on November 16, 2010, requesting that these companies withdraw or affirm their outstanding hearing requests under this docket within 30 days. On December 7, 2010, Pfizer withdrew its hearing request. On December 10, 2010, Actavis withdrew its hearing request.

FDA was unable to find current contact information for Bay Laboratories and National Pharmaceuticals. If either of these companies, or its successor-in-interest, continues to have an interest in pursuing its hearing requests under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that hearing requests that are not affirmed within that time frame are no longer being pursued, and will deem them withdrawn.

2. Dimetane Expectorant, Dimetane Expectorant-DC, and Actifed-C Expectorant; Docket 81N-0396 (DESI 6514)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22609), FDA revoked the temporary exemption that permitted the drug products described below, 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.

Dimetane Expectorant, containing brompheniramine maleate, phenylephrine hydrochloride, phenylpropanolamine hydrochloride, and guaifenesin, was marketed under NDA 11-694. Dimetane Expectorant-DC, containing codeine phosphate, brompheniramine maleate, phenylephrine hydrochloride, phenylpropanolamine hydrochloride, and guaifenesin, was marketed under NDA 11-694. Actifed-C Expectorant, containing codeine phosphate, triprolidine hydrochloride, pseudoephedrine hydrochloride, and guaifenesin, was marketed under NDA 12-575. All of these products were marketed as expectorants.

In response to the May 25, 1982, notice, timely hearing requests were filed by A.H. Robins Co., 1407 Cummings Dr., Richmond, VA 23220, for its products marketed under NDA 11-694; Bay Laboratories, 3654 West Jarvis, Skokie, IL 60076, for its IRS products Triphen Expectorant, Triphen Expectorant DC, and Pseudodine "C" Expectorant; Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709, for its product marketed under NDA 12-575; Cord Laboratories, Inc., 2555 W. Midway Blvd., Broomfield, CO 80020, for its IRS product, a syrup containing codeine phosphate, triprolidine hydrochloride, pseudoephedrine hydrochloride, and guaifenesin; Lederle Laboratories, 401 N. Middletown Rd., Pearl River, NY 10965, based on its distribution of Dimetane Expectorant; National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to Dimetane Expectorant, Dimetane Expectorant DC, and Actifed-C; and Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207, based on its distribution of an IRS product, Brompheniramine Maleate Expectorant.

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, on 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.

On September 14, 1984, FDA announced that it was withdrawing approval of those portions of NDA 12-575 pertaining to the old formulation of Actifed-C Expectorant (49 FR 36169), effective October 15, 1984, after the NDA holder, Burroughs Wellcome,

obtained approval for a reformulated version of the product and withdrew its hearing request. On October 25, 1984, Cord also withdrew its hearing request relating to this docket, based on discontinuation of the product that was the subject of the hearing request.

FDA sent letters to Pfizer, Inc., 235 East 42nd St., New York, NY 10017, successor to Lederle Laboratories, and to Actavis, 60 Columbia Rd., Building B, Morristown, NJ 07960, successor to Purepac Pharmaceuticals, on November 16, 2010, requesting that these companies withdraw or affirm their outstanding hearing requests under this docket within 30 days. On December 7, 2010, Pfizer withdrew its hearing request. On December 10, 2010, Actavis withdrew its hearing request.

FDA was unable to find current contact information for Bay Laboratories and National Pharmaceuticals. If either of these companies, or its successor-in-interest, continues to have an interest in pursuing its hearing request under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that hearing requests that are not affirmed within that time frame are no longer being pursued, and will deem them withdrawn.

3. Ambenyl Expectorant and Pyribenzamine and Ephedrine Tablets; Docket 82N-0095 (DESI 6514, 11935)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22604), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these product, 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.

Ambenyl Expectorant, containing codeine sulfate, bromodiphenhydramine hydrochloride, diphenhydramine hydrochloride, ammonium chloride, potassium guaiacolsulfonate, and menthol, was marketed under NDA 9-319. Pyribenzamine and Ephedrine Tablets, containing tripeleennamine hydrochloride and 12 mg ephedrine sulfate, were marketed under NDA 5-914.

In response to the May 25, 1982, notice, hearing requests were filed by Bay Laboratories, 3654 West Jarvis, Skokie, IL 60076, for Ambay Expectorant, its product IRS to Ambenyl Expectorant; Marion Laboratories, Inc.,

P.O. Box 9627, Kansas City, MO 64134, for its product marketed under NDA 9-319; and National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to Ambenyl Expectorant.

On 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, on August 24, 1984 (49 FR 33726), 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. On January 16, 1985, Bay Laboratories withdrew its hearing request relating to this docket.

FDA was unable to find current contact information for National Pharmaceuticals. If this company, or its successor-in-interest, continues to have an interest in pursuing its hearing request under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that if this hearing request is not affirmed within that time frame, it is no longer being pursued, and will deem it withdrawn.

4. Ornade Spansules; Docket 82N-0096 (DESI 12152)

In a notice published in the **Federal Register** on August 17, 1982 (47 FR 35870), FDA revoked the temporary exemption that permitted the drug product described below, and those products IRS to this product, to remain on the market beyond the time limit established for DESI. In the notice, FDA also announced the conditions for marketing these products, as reformulated, 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.

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. Prior to the publication of the August 17, 1982, **Federal Register** notice, Ornade

Spansules was reformulated to be a controlled-release product containing 12 mg chlorpheniramine maleate and 75 mg phenylpropanolamine.

In response to the August 17, 1982, notice, timely hearing requests were filed by B.F. Ascher & Co., 15501 West 109th St., Lenexa, KS 66219, for its IRS product Drize Slow-Release Capsules; Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, for its IRS product Profenade #2 S.R. Capsules; Glaxo, Inc 1011 North Arendell Ave, PO Box 1217, Zebulon, NC 27597, for its IRS product Histabid Duracaps; SmithKline & French Laboratories, 1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101, for its product marketed under NDA 12-152; and Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647, for its IRS product, a sustained release product containing chlorpheniramine and phenylpropanolamine. Two late hearing requests were filed by Knoll Pharmaceutical Co. (formerly Boots Pharmaceuticals, Inc.), 300 Tri-State International Center, suite 200, Lincolnshire, IL 60069, for its IRS product Ru-Tuss Tablets, and Pioneer Pharmaceuticals, Inc., 209 40th St., Irvington, NJ 07111, for its IRS product, characterized by the company as a generic version of Ornade Spansules. A late hearing request was also filed by Sidmak Laboratories, Inc., 17 West St., P.O. Box 371, East Hanover, NJ 07936, for two IRS products, one containing chlorpheniramine maleate 12 mg and phenylpropanolamine, and the other containing chlorpheniramine maleate 8 mg and phenylpropanolamine.

On 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. On January 15, 1986, SmithKline, the NDA holder for Ornade Spansules, withdrew its hearing request after receiving FDA approval for its supplemental NDAs covering the reformulated product. Knoll Pharmaceutical withdrew its hearing request relating to this docket on September 14, 1995.

On October 21, 2009, B.F. Ascher & Co. withdrew its hearing request relating to this docket. On the same date, Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, the successor-in-interest to Cord Laboratories, Inc., withdrew its hearing request. On February 15, 2010, Sidmak Laboratories' successor-in-interest, Teva

Pharmaceuticals, withdrew its hearing request.

On November 9, 2009, Glaxo's successor, GlaxoSmithKline, indicated it transferred its interest in Histabid Duracaps, the subject of its hearing request, to Medeva Pharmaceuticals sometime between 1984 and 1990, and GlaxoSmithKline indicated to the law firm that had filed the hearing request on behalf of Glaxo that it had no interest in pursuing the hearing request. The law firm was also able to contact UCB, the successor to the Celltech Chiroscience, which had previously acquired Medeva Pharmaceuticals. UCB also indicated to the law firm that had filed the hearing request that it had no interest in pursuing the hearing request filed by Glaxo for Histabid Duracaps. As the agency has not heard from UCB formally, the agency is providing the company an opportunity to affirm its hearing request in writing by the date specified in this notice. FDA will assume that if this hearing request is not affirmed within that time frame the request is no longer being pursued, and will deem it withdrawn.

FDA sent a letter to Zenith Laboratories on November 16, 2010 requesting that the company withdraw or affirm its outstanding hearing requests under this docket within 30 days. As of December 13, 2010, Zenith Laboratories had not responded to FDA.

FDA was unable to find current contact information for Pioneer Pharmaceuticals, Inc. If this company, or its successor-in-interest, continues to have an interest in pursuing its hearing request under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that if this hearing request is not affirmed within that time frame the request is no longer being pursued, and will deem it withdrawn.

5. Dimetapp Extentabs and Elixir; Docket 83N-0095 (DESI 11935)

In a notice published in the **Federal Register** on December 23, 1983 (48 FR 56854), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. In the notice, FDA also announced the conditions for marketing these products, as reformulated, 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 NDAs for the old formulations and for the indications

reclassified to lacking substantial evidence of effectiveness.

Dimetapp Extentabs, as formulated during the period of the DESI review, was a controlled-release product containing 12 mg brompheniramine maleate, 15 mg phenylephrine hydrochloride, and 15 mg phenylpropranolamine hydrochloride, and marketed under NDA 12-436. At the time of the publication of the December 23, 1983, **Federal Register** notice, the manufacturer had submitted a supplemental application proposing to reformulate the product to contain 12 mg brompheniramine maleate and 75 mg phenylpropranolamine hydrochloride in a controlled-release form. Dimetapp Elixir was originally formulated to contain 4 mg brompheniramine maleate, 5 mg phenylephrine hydrochloride, and 5 mg phenylpropranolamine hydrochloride per 5 milliliters (mL), and was marketed under NDA 13-087. At the time of the publication of the December 23, 1983, **Federal Register** notice, the manufacturer had submitted a supplemental application proposing to reformulate the product to contain 4 mg brompheniramine maleate and 25 mg phenylpropranolamine hydrochloride per 5 mL. The supplements to NDA 12-436 and NDA 13-087 were subsequently approved by FDA on April 20, 1984, and March 29, 1984, respectively.

In response to the December 23, 1983, notice, timely hearing requests were filed by A.H. Robins, 1407 Cummings Dr., Richmond, VA 23220, for its products marketed under NDA 12-436 and NDA 13-087; 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 Nalamine 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; Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, for Cordamine-PA Tablets, its product IRS to Dimetapp Extentabs; D.M. Graham Laboratories, Inc., Hobart, NY 13788, for unspecified IRS products; Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022, for its IRS products Brocon C.R. Tablets and Chewable Brocon Tablets; Halsey Drug Co. Inc., 1827 Pacific St., Brooklyn, NY 11233,

for its products IRS to Dimetapp Extentabs and Dimetapp Elixir; Lemmon Co., 850 Cathill Rd., Sellersville, PA 18960, for Phenatapp, its product 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 Expectoant, Tuss-Delay Tablets, Ban-Tuss Plain, Klerist-D Tablets, Respergen, Am-Tuss Liquid, Novadyne DH, Novadyne Expectoant, 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 23rd Ave. North, Minneapolis, MN 55441, for unspecified products. A late hearing request was filed by Sidmak Laboratories, Inc., 17 West St., P.O. Box 371, East Hanover, NJ 07936, for its products IRS to Dimetapp Extentabs.

On June 11, 1985, A.H. Robins, the NDA holder for Dimetapp Extentabs and Dimetapp Elixir, withdrew its hearing request relating to this docket, after reformulating its products to comply with the OTC monograph in part 341 (21 CFR part 341), "Cold, Cough, Allergy, Bronchodilator, and Antihistamine Drug Products for Over-the-Counter Human Use." Accordingly, on July 19, 1985 (50 FR 29484), FDA announced that it was withdrawing approval of those portions of NDAs 12-436 and 13-087 pertaining to the old formulations of the Dimetapp products, effective August 19, 1985.

On August 23, 1984, Lemmon Co. withdrew its hearing request relating to this docket. Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, the successor-in-interest to Cord Laboratories, Inc., withdrew its hearing request on October 21, 2009. Forest Laboratories, Inc., withdrew its hearing request on October 22, 2009. The

hearing request filed by D.M. Graham Laboratories, Inc., was withdrawn on December 10, 2009. D.M. Graham Laboratories was previously acquired by Mallinckrodt, Inc., which is now part of Covidien, 172 Railroad Ave., Hobart, NY 13788. Teva Pharmaceuticals, the successor-in-interest to Sidmak Laboratories, withdrew its hearing request on February 15, 2010. Acura Pharmaceutical Co., 616 N. North Court, Palantine, IL 60067, successor to Halsey Drug Co., withdrew its hearing request on November 23, 2010.

FDA sent a letter to Merz Pharmaceuticals, LLC, P.O. Box 18806, Greensboro, NC 27419, successor to Mayrand, Inc., Pharmaceuticals, on November 16, 2010, requesting that this company withdraw or affirm its outstanding hearing request under this docket within 30 days. As of December 13, 2010, the company had not responded to FDA.

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 Corporation; Copley Pharmaceutical, Inc.; LuChem Pharmaceuticals, Inc.; Pioneer Pharmaceuticals, Inc.; Quantum Pharmics, Ltd.; or Upsher-Smith Laboratories, Inc. If any of these companies, or their successors-in-interest, continue to have an interest in pursuing their hearing requests under this docket, the companies (or their successors-in-interest) must affirm their hearing requests in writing by the date specified in this notice. FDA will assume that hearing requests that are not affirmed within that time frame are no longer being pursued, and will deem them withdrawn.

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 FD&C Act. 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 part 341 (21 CFR part 341), "Cold, Cough, Allergy, Bronchodilator, and Antihistamine Drug Products for Over-the-Counter Human Use." OTC products that comply with this 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 the Federal Food, Drug, and Cosmetic Act (sections 502 and 505 (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: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-104 Filed 1-6-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0247]

FDA Transparency Initiative: Improving Transparency to Regulated Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: As part of the third phase of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled "FDA Transparency Initiative: Improving Transparency to Regulated Industry." The report includes 19 action items and 5 draft proposals to improve transparency to regulated industry. FDA is seeking public comment on the content of the draft proposals, as well as on which draft proposals should be given priority.

DATES: Submit electronic or written comments by March 8, 2011.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets at the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ann Witt, Office of Policy, Planning, and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, rm. 4226, Silver Spring, MD 20993, 301-796-7463, FAX: 301-847-8616, e-mail: Ann.Witt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the FDA Transparency Initiative

In January 2009, President Obama issued a memorandum on Transparency and Open Government calling for an "unprecedented level of openness in Government" and directing the Director of the Office of Management and Budget (OMB) to issue an Open Government Directive instructing executive departments and agencies to take specific actions to implement the principles of transparent, collaborative, and participatory government. The Open Government Directive was issued December 8, 2009. Under the leadership of Secretary of Health and Human Services, Kathleen Sebelius, the U.S. Department of Health and Human Services has also prioritized transparency and openness. In June 2009, the Commissioner of Food and Drugs (the Commissioner), Dr. Margaret Hamburg, launched FDA's Transparency Initiative to implement these efforts at FDA.

The initiative is overseen by a Task Force representing key leaders of FDA. The internal Task Force is chaired by the Principal Deputy Commissioner of FDA and includes five of the Agency's