TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]—Continued

Citation	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
21 CFR 101.105	12	2	24	0.5	12
Section 403(w)(1) of the FD&C Act	12	2	24	1	24
Guidance document entitled ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration''	12	1	12	1	12
Total					186

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents in table 1 is based on the number of regulatory submissions submitted to TTB for beers that do not meet the definition of a ''malt beverage'' under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTB estimates the number of respondents to be 12 and the number of disclosures annually to be 24. Thus, FDA adopts TTB's estimate of 12 respondents, and an annual number of disclosures per respondent of 2, in table 1 of this document.

FDA's estimate of the average burden per disclosure for each regulation are based on FDA's experience with food labeling under the Agency's jurisdiction. The estimated average burden per disclosure for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 in table 1 are equal to, and based upon, the estimated average burden per disclosure approved by OMB in OMB control number 0910–0381. FDA further estimates that the labeling burden of section 403(w)(1) of the FD&C Act, which specifies requirements for the declaration of food allergens, will be 1 hour based upon the similarity of the requirements to that of § 101.4. Finally, FDA estimates that a respondent will spend 1 hour reading the guidance document.

Thus, FDA estimates that 12 respondents will each label 2 products annually, for a total of 24 labels. FDA estimates that the manufacturers will spend 7.25 hours (0.5 hours + 1 hour + 0.25 hour + 4 hours + 0.5 hour + 1 hour = 7.25 hours) on each label to comply with FDA's labeling regulations and the requirements of section 403(w)(1) of the FD&C Act, for a total of 174 hours (24 labels × 7.25 hours = 174 hours). In addition, 12 respondents will each spend 1 hour reading the guidance document, for a total of 12 hours. Thus, FDA estimates the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours).

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 have been approved under OMB control number 0910–0381.

II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Memorandum of Understanding 225–88–2000 between FDA and Bureau of Alcohol, Tobacco and Firearms, available at *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm.*

2. TTB Ruling 2008–3 dated July 7, 2008, available at *http://www.ttb.gov/rulings/2008-3.pdf.*

Dated: July 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18028 Filed 7–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–1975–N–0336 (Formerly 75N–0184), FDA–1975–N–0355 (Formerly 75N–0185), FDA–1976–N–0272 (Formerly 76N–0056), FDA–1976–N–0344 (Formerly 76N–0057), FDA–1978–N–0701 (Formerly 78N–0070), FDA–1979–N–0224 (Formerly 79N–0169), FDA–1983–N–0297 (Formerly 83N–0030), and FDA–1988–N–0004 (Formerly 88N–0242); DESI 597, 1626, 3265, 10837, 12283, and 50213, and Hydrocortisone Acetate and Pramoxine Hydrochloride]

Drugs for Human Use; Drug Efficacy Study Implementation; Certain Prescription Drugs Offered for Various Indications; Opportunity To Affirm Outstanding Hearing Request

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is offering an opportunity to affirm outstanding hearing requests pertaining to several dockets. 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 August 23, 2012.

Hearing Requests: Hearing requests must be affirmed by notifying FDA by August 23, 2012. Hearing requests not affirmed within that timeframe will be deemed withdrawn.

ADDRESSES: Requests to affirm or withdraw outstanding hearing requests, as well as all other communications in response to this notice, should be identified with the appropriate docket number, and directed to Pamela Lee, Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5173, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Pamela Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5173, Silver Spring, MD 20993–0002, 301–796–3297, email: *pamela.lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is offering an opportunity to affirm outstanding hearing requests pertaining to FDA Docket Nos. FDA–1975–N–0336 (formerly 75N–0184) (DESI 597); FDA–1976–N–0272 (formerly 76N–0056), FDA–1976–N–0344 (formerly 76N–0057), and FDA–1978–N–0701 (formerly 78N–0070) (DESI 1626); FDA–1975–N–0355 (formerly 75N–0185) (DESI 3265); FDA–1975–N–0336 (formerly 75N–0184) (DESI 10837); FDA–1979–N–0224 (formerly 79N–0169) (DESI 12283); FDA–1983–N–0297 (formerly 83N–0030) (DESI 50213); and FDA–1988–N–0004 (formerly 88N–0242).

I. Background

When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) required that ''new drugs'' (see 21 U.S.C. 321(p)) be approved for safety by FDA before they could legally be sold in interstate commerce. To this end, the FD&C Act made it the sponsor's responsibility, before 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) (see (21 CFR 310.6(b)(1)) to the approved drug to be ''covered'' by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the FD&C Act to require that new drugs be proven effective for their labeled indications, as well as safe, 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 Sciences/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 reevaluated 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.

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 the 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 those indications, provided 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. Outstanding Hearing Requests Pertaining to Docket Nos. FDA–1975–N–0336 (Formerly 75N–0184) (DESI 597); FDA–1976–N–0272 (Formerly 76N–0056), FDA–1976–N–0344 (Formerly 76N–0057), and FDA–1978–N–0701 (Formerly 78N–0070) (DESI 1626); FDA–1975–N–0355 (Formerly 75N–0185) (DESI 3265); FDA–1975–N–0336 (Formerly 75N–0184) (DESI 10837); FDA–1979–N–0224 (Formerly 79N–0169) (DESI 12283); FDA–1983–N–0297 (Formerly 83N–0030) (DESI 50213); and FDA–1988–N–0004 (Formerly 88N–0242)

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 in this document contain pending hearing requests.

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

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 timeframe. 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 marketed and some 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. It should be noted that the discussion of DESI dockets does not provide a comprehensive historical record of each docket and, therefore, will not identify every request that had been previously addressed.

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 Pamela Lee (see **ADDRESSES**). The letter should include the docket number of the proceeding, as well as the name

and National Drug Code (NDC) 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 Pamela Lee (see **ADDRESSES**). 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 emailed by the date specified in this notice (see **DATES**). 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.

A. Certain Drug Products Containing an Anticholinergic in Combination With a Barbituate; Docket No. FDA–1975–N–0336 (Formerly 75N–0184) (DESI 597)

Under Docket No. FDA–1975–N–0336 (formerly 75N–0184), FDA determined that certain drug products containing an anticholinergic in combination with a barbiturate lacked substantial evidence of effectiveness for various gastrointestinal disorders, and offered an opportunity for hearing regarding its conclusion (48 FR 20495, May 6, 1983). In response to the May 1983 notice, the following companies filed timely hearing requests: A.H. Robins Co. (now part of Pfizer, Inc., 235 East 42nd St., New York, NY 10017), regarding Donnatal Tablets (ANDA 86–676), Capsules (ANDA 86–677), and Elixir (ANDA 86–661); B.F. Ascher & Co., Inc., 15501 W. 109th St., Lenexa, KS 66219, regarding Anaspaz-PB; Bay Laboratories, Inc., 3654 West Jarvis, Skokie, IL 60076, regarding Bay-Ase Elixir (ANDA 86–673); Beecham Laboratories, a Division of Beecham, Inc. (now part of Glaxo SmithKline, 200 N 16th St., #1, Philadelphia, PA 19102), regarding Hybephen (ANDA 86–573); Carter-Wallace, Inc. (now part of Meda Pharmaceuticals, Inc., 265 Davidson Ave., Suite 300, Somerset, NJ 08873–4120), regarding Barbidonna Tablets (ANDA 86–589), Barbidonna Elixir (ANDA 86–590), and Barbidonna No. 2 Tablets (ANDA 87–572); Ferndale Laboratories, Inc. (now part of Ferndale Pharma Group, Inc., 780 W. Eight Mile Rd., Ferndale, MI 48220), regarding Bellkatal Tablets and Pheno-Bella Tablets; Halsey Drug Co., Inc. (now part of Acura Pharmaceuticals, Inc., 616 N. North Court, Suite 120, Palatine, IL 60067), regarding Susano Elixir (ANDA 86–587) and Susano Tablets (ANDA 86–588); Kremers-Urban Co. (now part of Kremers-Urban Pharmaceuticals, Inc., 902 Carnegie Center, Suite 360, Princeton, NJ 08540), regarding Levsin with Phenobarbital Tablets (ANDA 86–640); Lemmon Co. (now part of Teva Pharmaceuticals, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454–1090), regarding Belladonna Alkaloids and Phenobarbital Tablets (ANDA 86–591); McNeil Pharmaceutical (now part of Ortho-McNeil-Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08568), regarding Butibel Tablets and Butibel Elixir (ANDA 86–664); National Pharmaceutical Manufacturing Co. (now part of Actavis US, 60 Columbia Rd., Bldg. B, Morristown, NJ 07960), regarding Barophen Elixir (ANDA 86–546) and Butabar Belladonna Elixir (ANDA 86–561); Purepac Pharmaceutical (now part of Actavis US, 60 Columbia Rd., Bldg. B, Morristown, NJ 07960), regarding Belladonna Alkaloids with Phenobarbital Tablets and Elixir; Reid-Provident Laboratories, Inc. (now part of Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064–3500), regarding Spalix Elixir (ANDA 86–652) and Spalix Tablets (ANDA 86–653); Richlyn Laboratories, Inc. (now part of Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544), regarding Bellophen (ANDA 86–687) and Spasmolin (ANDA 86–655); Sandoz, Inc., 506 Carnegie Center, Suite 400, Princeton, NJ 08540, regarding Belladenal Tablets (ANDA 86–668) and Belladenal S Tablets (ANDA 87–198); Stuart Pharmaceuticals, Division of ICI Americas, Inc. (now part of AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850–5437), regarding Kinesed Tablets; Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102, regarding Barbeloid Tablets, Green (NDA 85–532) and Barbeloid Tablets, Yellow (NDA 86–549); West-ward Pharmaceutical Corp., 401 Industrial Way West, Eatontown, NJ 07724–2206, regarding Belladonna Alkaloid with Phenobarbital Tablets; William P. Poythress & Co., Inc., 16 N. 22nd St., P.O. Box 26946, Richmond, VA 23261, regarding unidentified products composed of atropine sulfate 0.195 milligrams (mg) in combination with phenobarbital 16 mg; William Rorer, Inc. (now part of Sanofi-Aventis U.S., 55 Corporate Dr., Bridgewater, NJ 08807), regarding Chardonna-2 Tablets (ANDA 86–585); and Wharton Laboratories, Inc., 48th Ave., Long Island City, NY 11101, regarding Bellastal Capsules (ANDA 86–657).

In May, June, and July 2011, FDA sent letters to the following companies requesting that they withdraw or affirm their outstanding hearing requests under this docket within 30 days: Pfizer, Inc.; B.F. Ascher & Co., Inc.; Glaxo SmithKline; Meda Pharmaceuticals, Inc.; Ferndale Pharma Group, Inc.; Acura Pharmaceutical Co.; Kremers-Urban Pharmaceuticals, Inc.; Teva Pharmaceuticals; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Actavis US; Abbott Laboratories; Impax Laboratories, Inc.; Sandoz, Inc.; AstraZeneca Pharmaceuticals LP; West-ward Pharmaceutical Corp.; and Sanofi-Aventis U.S.

On May 24, 2011, Actavis US withdrew the hearing request filed by National Pharmaceutical Manufacturing Co. On May 26, 2011, Teva Pharmaceuticals and Impax Laboratories, Inc., withdrew the hearing requests filed by Lemmon Co. and Richlyn Laboratories, Inc., respectively. On June 2, 2011, Ferndale Pharma Group, Inc., withdrew its hearing request. On June 3, 2011, AstraZeneca Pharmaceuticals, LP, withdrew the hearing request filed by Stuart Pharmaceuticals. On June 6, 2011, Acura Pharmaceutical Co. withdrew the hearing request filed by Halsey Drug Co., Inc. On June 7, 2011, Johnson & Johnson Pharmaceutical Research & Development, LLC, responded to the letter sent to Ortho-McNeil-Janssen Pharmaceuticals, Inc., stating that the rights to Butibel Elixir had been transferred to Carter Wallace in 1982. On June 20, 2011, B.F. Ascher & Co., Inc., withdrew its hearing request. On June 22, 2011, Novartis Pharmaceuticals Corp., the successor-in-interest by merger to Sandoz, Inc., withdrew Sandoz, Inc.'s hearing request. On July 7, 2011, Meda Pharmaceuticals, Inc., withdrew the hearing request filed by Carter-Wallace, Inc., as well as the hearing request filed by McNeil Pharmaceutical for Butibel Tablets and Elixir. On July 27, 2011, Kremers-Urban Co. withdrew its hearing request. On August 11, 2011, GlaxoSmithKline withdrew the hearing request filed by Beecham Laboratories. On August 24, 2011, Abbott Laboratories withdrew the hearing request filed by Reid-Provident Laboratories, Inc.

On July 6, 2011, West-ward Pharmaceutical Corp. affirmed its hearing request and PBM Pharmaceuticals, Inc., affirmed the hearing request filed by A.H. Robins Co., as the asserted successor-in-interest to A.H. Robins Co.'s hearing request. A **Federal Register** notice issued on June 8, 2011 (76 FR 33310), withdrew the approval of 70 NDAs and 97 ANDAs. This included the withdrawal of the approval for Donnatal Capsules and

withdrawal of the conditional approval for the Donnatal Tablets and Elixir. This withdrawal notice was subsequently corrected to note that the approval and conditional approvals for these products were still in effect, because PBM Pharmaceuticals, Inc., had acquired the rights to the ANDAs and had informed FDA before the withdrawal would have become effective that it did not want the ANDAs withdrawn (76 FR 79701, December 22, 2011).

As of April 1, 2012, Actavis U.S. (with respect to the hearing request filed by Purepac Pharmaceutical) and Sanofi-Aventis U.S. had not responded to FDA. FDA was unable to find current contact information for Bay Laboratories, Inc.; Vale Chemical Co., Inc.; William P. Poythress & Co., Inc.; and Wharton Laboratories, Inc. If any of these companies, or any successor-in-interest, continues to have an interest in pursuing its hearing request under this docket, the companies (or their successors-in-interest) must affirm their hearing requests in writing by the date specified in this notice (see **DATES**). FDA will assume that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.

B. Combination Drugs Containing a Xanthine Derivative; Docket No. FDA–1976–N–0272 (Formerly 76N–0056), FDA–1976–N–0344 (Formerly 76N–0057), and FDA–1978–N–0701 (Formerly 78N–0070) (DESI 1626)

In 1972, FDA classified certain combination drug products containing a xanthine derivative as less than effective for some labeled indications and possibly effective for other labeled indications (37 FR 14895, July 26, 1972). As described in a **Federal Register** notice of February 29, 1984, FDA subsequently handled these products in three groups: (1) Combinations containing more than 2 grains of xanthine derivative, more than 8 mg of phenobarbital, and/or an ingredient not considered as part of the over-the-counter (OTC) drug review (Docket No. FDA–1976–N–0272 (formerly 76N–0056)); (2) combinations containing 2 grains or less of a xanthine derivative, ephedrine, and 8 mg or less of phenobarbital (Docket No. FDA–1976–N–0344 (formerly 76N–0057)); and (3) combinations containing theophylline, ephedrine, and hydroxyzine hydrochloride (HCl) (Docket No. FDA–1978–N–0701 (formerly 78N–0070)) (49 FR 7454, February 29, 1984).

In 1976, FDA reclassified certain combination preparations containing a xanthine derivative to lacking substantial evidence of effectiveness, proposed withdrawing associated NDAs, and offered an opportunity for hearing regarding its proposal (41 FR 15051, April 9, 1976). The group of products addressed in the April 1976 notice contained more than 2 grains of xanthine derivative, a barbiturate in higher strength than the equivalent of 8 mg of phenobarbital, and/or an ingredient not considered as part of the OTC drug review (Docket No. FDA–1976–N–0272 (formerly 76N–0056)) (id.). The holders of the NDAs listed in the April 1976 notice did not request hearings, and those NDAs were withdrawn in October 1977 (42 FR 54620, October 7, 1977). However, in response to the April 1976 notice, the following companies filed timely hearing requests: Knoll Pharmaceutical Co. (now part of Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064–3500), regarding Quadrinal Tablets and Suspension, and Mead Johnson Laboratories (now Mead Johnson Nutrition, 4th Floor, 2701 Patriot Blvd., Glenview, IL 60026), regarding Quibron Plus Capsules and Elixir.

In 1984, FDA amended the April 1976 notice to include its analysis of new information regarding combination products containing a xanthine derivative (49 FR 7454, February 29, 1984). Based on its analysis of the new information, FDA concluded that there is a lack of substantial evidence that: (1) Each ingredient contributes to the claimed effect of such combination drug products, and (2) the dosage of each component is such that the combinations are safe and effective for a significant patient population (id.). Therefore, FDA proposed in the 1984 notice to withdraw approval of the applications for combination products containing a xandine derivative, and offered an opportunity for hearing regarding its proposal. In response to the February 1984 notice, the following companies filed timely hearing requests: National Pharmaceutical Manufacturing Co. (now part of Actavis US, 60 Columbia Rd., Bldg. B, Morristown, NJ 07960), regarding Brondelate Elixir, Ferdinal Suspension, Guiaphed Elixir, Hydroxyzine Compound Syrup, Iophylline Elixir, Isolate Compound Elixir, and Theofed Suspension and Liquid; Warner Lambert Co. (now part of Pfizer, Inc., 235 East 42nd St., New York, NY 10017), regarding Tedral SA; and William P. Poythress & Co., Inc., 16 N. 22nd St., P.O. Box 26946, Richmond, VA 23261, regarding an unidentified product containing a xanthine derivative, ephedrine, and 8 mg or less of phenobarbital.

In March and April 2011, FDA sent letters to Abbott Laboratories, Actavis US, Mead Johnson Nutrition, and Pfizer, Inc., requesting that these companies withdraw or affirm their outstanding hearing requests under this docket within 30 days.

On April 25, 2011, Mead Johnson Nutrition withdrew the hearing request filed by Mead Johnson Laboratories. On May 3, 2011, Pfizer, Inc. withdrew the hearing request filed by Warner Lambert Co. On May 9, 2011, Actavis US withdrew the hearing request filed by National Pharmaceutical Manufacturing Co. On June 21, 2011, Abbott Laboratories withdrew the hearing request filed by Knoll Pharmaceutical Co.

FDA was unable to find current contact information for William P. Poythress & Co. 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 (see **DATES**). FDA will assume that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.

C. Certain Single Entity Antispasmodic Drugs; Docket No. FDA–1975–N–0355 (Formerly 75N–0185) (DESI 3265)

In 1971, FDA published DESI efficacy findings for single-ingredient anticholinergic drugs for oral or injectable use containing dicyclomine HCl and piperidolate HCl, among other ingredients (36 FR 11754, June 18, 1971). In a notice published on November 11, 1975 (40 FR 52644), FDA determined that the June 18, 1971, **Federal Register** notice should not have included drugs containing certain specified ingredients, including dicyclomine HCl and piperidolate HCl, because the drugs containing those ingredients were not anticholinergic drugs. Also on November 11, 1975, FDA published a notice of opportunity for hearing regarding these drugs (40 FR 52649). In response to the November 1975 notice, the following companies filed timely hearing requests: Carnrick Laboratories, Inc., 65 Horsehill Rd., Cedar Knolls, NJ 07927, regarding Midrin, and Merrell-National Laboratories, 110 Amity Rd., Cincinnati, OH 45215, regarding Bentyl Capsules (NDA 7–409), Bentyl Injection (NDA 8–370), Bentyl Syrup (NDA 7–961), and Dactil Tablets (NDA 8–907).

In September 2011, FDA sent letters to counsel for Carnrick Laboratories, Inc., which FDA believed operated as a subsidiary of Elan Corporation PLC, and

to Sanofi-Aventis U.S., which FDA believes to be the successor-in-interest to Merrell-National Laboratories. In September 2011, Carnrick Laboratories, Inc.'s former counsel informed FDA that it did not represent Carnrick Laboratories, Inc., or Elan Corporation PLC with respect to the hearing request under DESI 3265. In October 2011, FDA sent a letter to Sun Pharmaceutical Industries, Inc., believing it to be the successor-in-interest to Carnrick Laboratories, Inc.'s hearing request. On November 3, 2011, a representative from Sun Pharmaceutical Industries, Inc., verbally informed FDA that it was withdrawing the hearing request filed by Carnrick Laboratories, Inc., and stated they would be submitting their withdrawal of the hearing request in writing.

As of April 1, 2012, Sanofi-Aventis U.S. has not responded to FDA. If this company, or the successor-in-interest, continues to have an interest in pursuing the hearing request filed by Merrell-National Laboratories under this docket, the company (or its successor-in-interest) must affirm the hearing request in writing by the date specified in this notice (see **DATES**). FDA will assume that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.

D. Certain Anticholinergics/ Antispasmodics in Combination With a Sedative, and Single-Entity Antispasmodics, in Conventional Dosage Form; Docket No. FDA–1975–N–0336 (Formerly 75N–0184) (DESI 10837)

Through DESI review, FDA determined that two products, Pathibamate and Milpath Tablets, both containing tridihexethyl chloride and meprobamate, were possibly effective as adjunctive therapy in peptic ulcer and in the irritable bowel syndrome, functional diarrhea, drug-induced diarrhea, ulcerative colitis, urinary bladder spasm, and urethral spasm (36 FR 11875, June 22, 1971). In 1981, FDA reclassified these products to lacking substantial evidence of effectiveness, proposed withdrawing associated NDAs, and offered an opportunity for hearing regarding its proposal (46 FR 3977, January 16, 1981). In response to the January 1981 notice, the following companies filed timely hearing requests: Cord Laboratories (now part of Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020), regarding Chlordinium Capsules (ANDA 86–667); Roche Laboratories (now part of Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080–4990), regarding Librax; and Premo Pharmaceutical Laboratories, Inc. (now part of Teva Pharmaceuticals, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454–1090), regarding Meprohex 200 (ANDA 86–674), Meprohex 400 (ANDA 86–658), and chlordinium capsules (ANDA 86–667).

FDA sent letters to Genentech, Inc., in November 2010, and to Sandoz, Inc., and counsel of record for Premo Pharmaceutical Laboratories, Inc., in January 2011, requesting that these companies withdraw or affirm their outstanding hearing requests under this docket within 30 days. At the time, FDA was unable to find a current address for Premo Pharmaceutical Laboratories, Inc., and did not know that the company is part of Teva Pharmaceuticals.

On February 4, 2011, Genentech, Inc., informed FDA that it was no longer interested in pursuing the hearing request filed by Roche Laboratories, but noted that it had sold the rights of the product that was the subject of the hearing request to Valeant Pharmaceuticals International, Inc. On February 28, 2011, Sandoz, Inc., withdrew the hearing request filed by Cord Laboratories. On March 15, 2011, Teva Pharmaceuticals withdrew the hearing request filed by Premo Pharmaceutical Laboratories, Inc.

In March 2011, FDA sent a letter to Valeant Pharmaceuticals International, Inc., requesting that the company withdraw or affirm the outstanding hearing request filed by Roche Laboratories under this docket within 30 days. As of April 1, 2012, Valeant Pharmaceuticals International, Inc., had not responded to FDA. 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 (see **DATES**). FDA will assume that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.

E. Chlorthalidone; Docket No. FDA–1979–N–0224 (Formerly 79N–0169) (DESI 12283)

In 1979, as part of the DESI review, FDA announced its conclusions regarding the effectiveness of chlorthalidone for the treatment of hypertension and certain types of edema (44 FR 54124, September 18, 1979). Specifically, FDA determined that there was substantial evidence to support the effectiveness of the 25- and 50-mg strengths for use in hypertension, but that there was no longer justification for the 100-mg dosage form of chlorthalidone because of safety concerns at that dosage level (id. at 54126). The 1979 notice proposed to withdraw approval of the 100-mg strength and offered an opportunity for hearing regarding its proposal. In response to the 1979 notice, the following companies filed timely hearing requests: Generics International Division of Apotex, Inc., 2400 North Commerce Pkwy., suite 400, Weston, FL 33326, regarding Chlorthalidone, and USV Pharmaceutical Corp. (now part of Sanofi-Aventis U.S., 55 Corporate Dr., Bridgewater, NJ 08807), regarding Hygroton (NDA 12–283).

FDA sent letters to Sanofi-Aventis U.S. and Apotex, Inc., in May 2011 and July 2011, respectively, requesting that the companies withdraw or affirm their outstanding hearing requests under this docket within 30 days.

On August 12, 2011, Sanofi-Aventis U.S. withdrew the outstanding hearing request filed by USV Pharmaceutical Corp. As of April 1, 2012, Apotex, Inc., had not responded to FDA. 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 (see **DATES**). FDA will assume that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.

F. Chlortetracycline and Tetracycline; Docket No. FDA–1983–N–0297 (Formerly 83N–0030) (DESI 50213)

Through DESI review, FDA determined that certain fixed-combination drugs containing antibiotics and sulfonamides lack substantial evidence of effectiveness (34 FR 6008, April 2, 1969). The April 1969 **Federal Register** notice proposed to revoke provisions for certification of these products and offered interested persons 30 days to submit data concerning the proposal. Data submitted in response to the April 1969 notice did not provide substantial evidence of effectiveness, so FDA amended the antibiotic regulations on June 30, 1970, by revoking provisions for the certification of these drugs (35 FR 10587, June 30, 1970). The order was to become effective in 40 days, and allowed 30 days for interested persons to file objections and request a hearing. The time for responding to the June 1970 order was subsequently extended until August 17, 1970 (35 FR 12653, August 8, 1970).

In response to the June 1970 order, Pfizer, Inc., submitted data regarding its

affected product, Urobiotic 250 Capsules, and requested a hearing. Despite the filing of timely objections, the amendments were inadvertently not stayed, and succeeding codifications of the antibiotic regulations did not explicitly provide for certification of Urobiotic 250 Capsules. However, FDA permitted Pfizer, Inc., to continue distribution of its product pending resolution of the firm's hearing request. In July 2010, Pfizer, Inc., voluntarily withdrew its application for Urobiotic (*see* 75 FR 42455, July 21, 2010), but its hearing request remains pending.

In October 2010, FDA sent Pfizer, Inc., a letter requesting that it withdraw or affirm its outstanding hearing request under this docket within 30 days. As of April 1, 2012, Pfizer, Inc., had not responded to FDA. If Pfizer, Inc. (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 (see **DATES**). FDA will assume that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.

G. Hydrocortisone Acetate and Pramoxine HCl; Docket No. FDA–1988–N–0004 (Formerly 88N–0242)

Through DESI review, FDA determined that topical corticosteroids, including hydrocortisone acetate, were effective for symptomatic relief and adjunctive management of various steroid-responsive dermatoses (36 FR 7982, April 28, 1971). In the mid-1970s, FDA approved several products under ANDAs listing hydrocortisone acetate as their sole active ingredient. Subsequently, FDA determined that these products also contained an anesthetic active ingredient, pramoxine HCl. FDA evaluated the effectiveness of the fixed-combination and found no evidence that the pramoxine HCl component contributes an effect to the combination drug (53 FR 25013, July 1, 1988). Thus, FDA proposed to withdraw the ANDAs for these products and offered an opportunity for hearing on its proposal (id).

In response to the July 1988 notice, the following companies filed timely hearing requests: Copley Pharmaceutical, Inc., 398 West Second St., Boston, MA 02127, regarding a topical aerosol foam hydrocortisone and pramoxine HCl product (ANDA 89–440); Ferndale Laboratories, Inc. (now part of Ferndale Pharma Group, Inc., 780 W. Eight Mile Rd., Ferndale, MI 48220), regarding Pramosone lotion (0.5% hydrocortisone acetate) (ANDA 83–213), Pramosone cream (0.5% hydrocortisone acetate) (ANDA 83–778), Pramosone cream (1.0% hydrocortisone acetate) (ANDA 85–368), Pramosone lotion (1.0% hydrocortisone acetate) (ANDA 85–979), Pramosone lotion (2.5% hydrocortisone acetate) (ANDA 85–980), Pramosone ointment (1% hydrocortisone acetate), Pramosone ointment (2.5% hydrocortisone acetate), Pramosone cream (2.5% hydrocortisone acetate), Enzone cream, Zone-A lotion, Zone-A Forte lotion, Zone-A cream, FEP cream, Dibucort cream, and Procto-cream HC; and Reed & Carnrick (now part of Meda Pharmaceuticals, Inc., 265 Davidson Ave., suite 300, Somerset, NH 08873–4120), regarding its topical aerosol foam hydrocortisone and pramoxine HCl products (ANDAs 86–195 and 86–457).

In November 2010, FDA sent letters to Copley Pharmaceutical, Inc.; Ferndale Pharma Group, Inc.; and Meda Pharmaceuticals, Inc., requesting that these companies (or their successors-in-interest) withdraw or affirm their outstanding hearing requests under this docket within 30 days. On January 3, 2011, counsel for Ferndale Laboratories, Inc., and Meda Pharmaceutical, Inc., sent a letter affirming the hearing requests made by both companies.

As of April 1, 2012, Copley Pharmaceutical, Inc., had not responded to FDA. 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 (see **DATES**). FDA will assume that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 502 and 505 (21 U.S.C. 352 and 355)).

Dated: July 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18015 Filed 7–23–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding Section 340B of the Public Health Service Act Registration Period

AGENCY: Department of Health and Human Services, Health Resources and Services Administration.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing this notice to inform stakeholders of the revised deadlines for registration of new covered entities and for adding outpatient facilities and contract pharmacy arrangements to the 340B Drug Pricing Program (340B Program).

DATES: Effective Date: October 1, 2012.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 340B(a)(4) of the Public Health Service Act (PHS) Act (42 U.S.C. 256b) lists the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program. For a complete list of eligible entities, visit the OPA Web site at *http://www.hrsa.gov/opa.introduction.htm*. Eligibility for participation in the 340B Program is limited to the categories of entities specified in this section of the statute. Section 340B(a)(9) of the PHS Act requires the Secretary to notify participating manufacturers of the identity of those entities that meet the definition of covered entity under 340B(a)(4). HRSA published final guidelines on the participation of outpatient facilities in the **Federal Register** at 59 FR 47884 (Sept. 19, 1994). HRSA published final guidelines on the utilization of Contract Pharmacy Arrangements in the **Federal Register** at 75 FR 10272 (March 5, 2010).

II. Registration Deadlines

This notice replaces all previous 340B Program guidance documents addressing the deadline and enrollment period for the 340B Program registration of new covered entities, addition of outpatient facilities and contract pharmacies, including any individual