or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt a HUD from the effectiveness requirements under sections 514 and 515 of the act, provided that the device meets requirements set forth under section 520(m) of the act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of a HUD is in compliance with the HUD provisions under section 520(m) of the act.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.102	14	1	14	40	560
814.104	6	1	6	320	1,920
814.106	6	2	12	50	600
814.108	32	1	32	80	2,560
814.116(e)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.24(b)	4	1	4	2	8
814.126(b)(1)	45	1	45	120	5,400
Total					11,054

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
814.126(b)(2)	45	1	45	2	90
Total					90

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

The number of respondents in Tables 1 and 2 of this document are an average from data for the previous 3 years, i.e., FY 2005–2007. The number of annual reports submitted under § 814.126(b)(1) in Table 1 reflects an increase to 45 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in Table 2, the number of recordkeepers increased to 45.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: September 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22991 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0506]

Determination That ATROVENT (Ipatropium Bromide) Inhalation Solution and 10 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the 11 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term

Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR § 10.25(a) and § 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 20–228 for ATROVENT (ipratropium bromide) Inhalation Solution in the **Federal Register** of November 7, 2007 (72 FR 62858).)

Application No.	Drug	Applicant
NDA 20–228	ATROVENT (ipratropium bromide) Inhalation Solution, 0.02%	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368
NDA 20–306	Fludeoxyglucose F–18 (4–40 millicuries (mCi)/milliliter (mL) and 4–90 mCi/mL) Injection	Downstate Clinical PET Center, Methodist Medical Center, 112 Crescent Ave., Peoria, IL 61606
NDA 20–333	AGRYLIN (anagrelide hydrochloride (HCl)) Capsules, equivalent to (EQ) 1 milligram (mg) base	Shire US Inc., 725 Chesterbrook Blvd., Wayne, PA 19087–5637
NDA 20–377	CORDARONE (amiodarone HCl) Injection, 50 mg/mL	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 20–974	PROZAC (fluoxetine HCl) Tablets, EQ 10 mg base	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 50–417	NEOSPORIN (bacitracin zinc; neomycin sulfate; polymyxin B sulfate) Ophthalmic Ointment, 400 units/gram (g); EQ 3.5 mg base/g; 10,000 units/g	Monarch Pharmaceuticals, Inc., c/o King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620
NDA 50–461	ANCEF (cefazolin sodium) Injection, 250 mg/vial, 500 mg/vial, and 5 g/vial	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406
NDA 50–521	CECLOR (cefaclor) Capsules, EQ 250 mg and 500 mg base	Eli Lilly and Co.
NDA 50–522	CECLOR (cefaclor) Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	Do.
NDA 50–527	DURICEF (cefadroxil) Oral Suspension, EQ 125 mg base/5 mL	Warner Chilcott, Inc., Rockaway 80 Corporate Center, 100 Enterprise Dr., suite 280, Rockaway, NJ 07866
ANDA 61–229	POLYSPORIN (bacitracin zinc; polymyxin B sulfate) Ophthalmic Ointment, 500 units/g; 10,000 units/g	Monarch Pharmaceuticals, Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued

marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: September 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23035 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0484]

Preparation for International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is announcing a correction to the notice of a public meeting entitled ''Preparation for International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting.'' This meeting was announced in the **Federal Register** of September 16, 2008 (73 FR 53428). The correction is being made to reflect changes in the *Summary*, *Date and Time*, *Location*, *Contact Person*, *Background*, and *Agenda* portions of the document.

FOR FURTHER INFORMATION CONTACT: Tammie Jo Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by email: *Tammie.Bell2@fda.hhs.gov* or fax: 301–827–0003.

SUPPLEMENTARY INFORMATION: The FDA is correcting a notice published in the **Federal Register** of September 16, 2008 (73 FR 53428), announcing a meeting entitled ''Preparation for International Conference on Harmonization Meetings in Brussels, Belgium.'' This corrected notice is being published in its entirety:

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for International Conference on Harmonization Meetings in Brussels, Belgium'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Brussels, Belgium. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Brussels, Belgium, November 10 to 13, 2008, at which discussion of the topics underway and the future of ICH will continue, as well as provide comprehensive updates of the various ICH topics.

Date and Time: The meeting will be held on Tuesday, October 21, 2008, from 2:30 p.m. to 5:30 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd floor, Conference Rooms D and E, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 2:15 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to Conference Rooms D and E.

Contact Person: All participants must register with Tammie Jo Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by email: *Tammie.Bell2@fda.hhs.gov* or fax: 301–827–0003.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentation, to the contact person by October 14, 2008.

If you need special accommodations due to a disability, please contact Tammie Jo Bell at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–66, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Background: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufactures Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 14, 2008, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and email of proposed participants, and an indication of the approximate time requested to make their presentation.

Agenda: The agenda for the public meeting will be made available via the internet at *http://www.fda.gov/cder/meeting/ICH_20081021.htm*.