TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1271.160(b)(3) and (b)(6)	1,694	12	20,328	1	20,328
1271.160(d)	1,694	12	20,328	1	20,328
1271.190(d)(2)	1,694	12	20,328	1	20,328
1271.195(d)	1,694	12	20,328	1	20,328
1271.200(e)	1,694	12	20,328	1	20,328
1271.210(d)	1,694	12	20,328	1	20,328
1271.230(a)	1,694	12	20,328	1	20,328
1271.230(c)	1,694	1	1,694	1	1,694
1271.260(d)	1,694	12	20,328	.25	5,082
1271.260(e)	1,694	365	618,310	.083	51,526
1271.265(c)(1)	1,694	1,196	2,026,024	.083	168,835
1271.265(c)(3)	847	1	847	1	847
1271.265(e)	1,694	1,196	2,026,024	.083	168,835
1271.270(a)	1,694	1,196	2,026,024	.25	506,506
1271.270(e)	1,824	2	3,648	.5	1,824
1271.290(d) and (e)	1,694	51	86,394	.25	21,599
1271.320(b)	1,141	5	5,705	1	5,705
Total					1,967,496

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Sections 1271.47(a), 1271.85(b)(2), 1271.160(b)(2) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b), 1271.200(c), 1271.230(a), 1271.250(a), and 1271.265(e).

Dated: March 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5229 Filed 3–10–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0109]

Determination That PRO–BANTHINE (Propantheline Bromide) Tablets and 14 Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the 15 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 12–097 for KENALOG IN ORABASE (triamcinolone acetonide) Dental Paste in the **Federal Register** of February 11, 2009 (74 FR 6896).)

Application No.	Drug	Applicant
NDA 8–732	PRO–BANTHINE (propantheline bromide) Tablets, 7.5 milligrams (mg) and 15 mg	Shire Pharmaceuticals, Inc.,725 Chesterbrook Blvd., Wayne, PA 19087)
NDA 12–097	KENALOG IN ORABASE (triamcinolone acetonide) Dental Paste, 0.1%	Apothecon, Inc., c/o Bristol-Myers Squibb, P.O. Box 4500, Princeton, NJ 08543–4500
NDA 12–141	CYTOXAN (cyclophosphamide) Tablets, 25 mg and 50 mg	Baxter Healthcare Corp., 1620 Waukegan Rd. MPGR–AL, McGaw Park, IL 60085
NDA 17–498	MICRONASE (glyburide) Tablets, 1.25 mg, 2.5 mg, and 5 mg	Pharmacia and Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49001
NDA 17–924	TAGAMET (cimetidine HCl) Oral Solution, Equivalent to (EQ) 300 mg base/5 mL	GlaxoSmithKline, 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709–3398
NDA 18–207	DESYREL (trazodone HCl) Tablets, 50 mg, 100 mg, 150 mg, and 300 mg	Apothecon, Inc.
NDA 19–425	TRANDATE (labetalol HCl) Injection, 5 mg/mL	Prometheus Laboratories, Inc., 9410 Carroll Park Dr., San Diego, CA 92121
NDA 20–101	PROZAC (fluoxetine HCl) Oral Solution, EQ 20 mg base/5 mL	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 20–286	MONOPRIL–HCT (fosinopril sodium; hydrochlorothiazide) Tablets, 10 mg/12.5 mg, 20 mg/12.5 mg	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000
NDA 20–664	DOSTINEX (cabergoline) Tablet, 0.5 mg	Pharmacia and Upjohn Co.
NDA 20–683	ALESSE (ethinyl estradiol; levonorgestrel) Tablets (21 Tablets and 28 Tablets), 0.02 mg; 0.1 mg	Wyeth Pharmaceuticals Inc., P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 20–801	PEPCID AC (famotidine) Chewable Tablet, 10 mg	Merck Research Laboratories, Sumneytown Pike BLA 20, P.O. Box 4, West Point, PA 19486–0004
NDA 20–860	LEVLITE (ethinyl estradiol; levonorgestrel) Tablets (21 Tablets and 28 Tablets), 0.02 mg; 0.1 mg	Bayer Healthcare Pharmaceuticals, Inc., 340 Changebridge Rd., P.O. Box 1000, Montville, NJ 07045–1000
NDA 21–455	BONIVA (ibandronate sodium) Tablet, EQ 2.5 mg base	Hoffmann LaRoche, Inc., 340 Kingsland St., Bldg. 719/4, Nutley, NJ 07110–1199
NDA 50–517	MEFOXIN (cefoxitin sodium) Injection, EQ 1 gram (g) base/vial and EQ 2 g base/vial	Merck and Co., Inc., Sumneytown Pike BLA 20, P.O. Box 4, West Point, PA 19486–0004

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: March 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5275 Filed 3–10–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 14, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Anuja.Patel@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 14, 2010, the committee will: (1) Receive presentations from the Office of Generic Drugs (OGD) on a proposal for revision of the bioequivalence (BE) approaches, specifically to discuss the addition of a limitation on point estimates; (2) receive presentations on an awareness topic to highlight some issues associated with product instability (failure of a marketed product to meet stability specifications through the expiration date), and the potential research needs to address those issues; and (3) receive and discuss presentations from Office of Pharmaceutical Science (OPS) on the regulatory challenges of drug-induced phospholipidosis (excessive intracellular accumulation of phospholipids, a kind of fatty molecule, due to the use of certain drugs).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 30, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 22, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 23, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Anuja Patel at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 8, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–5264 Filed 3–10–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: June 17, 2010.

Closed: 8:30 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Open: 11 a.m. to 5 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by