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that hearing requests that are not affirmed within that timeframe are no longer being pursued, and will deem them withdrawn.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]

BILLING CODE 4160–01–P

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

correspondence issued by HRSA on the subject.

(A) Registration Period for New Covered Entities and for the Addition of Outpatient Facilities

The registration period for 340B Program registration of new covered entities and the addition of outpatient facilities shall be limited to the following: January 1–January 15 for an effective start date of April 1; April 1–April 15 for an effective start date of July 1; July 1–July 15 for an effective start date of October 1; and October 1–October 15 for an effective start date of January 1.

In situations where the 15th falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day. Covered entities will not be able to submit registrations outside of these date parameters listed above except when the Secretary has declared a Public Health Emergency. In addition to the complete on-line registration, any required supporting documentation must be submitted on the same day as on-line registration is completed. Incomplete packages will not be considered. For more information on what constitutes a complete package, visit the Office of Pharmacy Affairs (OPA) Web site at *www.hrsa.gov/opa.*

(B) Registration Period for Contract Pharmacies

The registration period for 340B Program registration of contract pharmacies shall be limited to the following: January 1–January 15 for an effective start date of April 1; April 1–April 15 for an effective start date of July 1; July 1–July 15 for an effective start date of October 1; and October 1–October 15 for an effective start date of January 1.

In situations where the 15th falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day. The contract pharmacy registration process is not complete unless the registration form has been completed in its entirety and the original, signed copy is received by OPA.

Signed contract pharmacy registration forms are due to OPA within 15 days from the time online registration was completed. Incomplete packages will not be considered. For more information on what constitutes a complete package, visit the OPA Web site at *www.hrsa.gov/opa.*

(C) Other Deadlines

Deadlines for forms other than those listed above are not affected by this notice. For example, change requests are not affected by this notice and will be processed as they are received.

Dated: July 17, 2012.

Mary K. Wakefield,

Administrator.

[FR Doc. 2012–17969 Filed 7–23–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and (6), Title 5 U.S.C., as amended. The grant applications 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, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Jackson Heart Study RFA Review.

Date: August 15, 2012.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, *creazzotl@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; National Health Survey Proposals.

Date: August 15, 2012.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Stephanie J Webb, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–435–0291, *stephanie.webb@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 18, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18071 Filed 7–23–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

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

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

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NET–PD Competitive Renewal Review.

Date: August 20, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Chicago O'Hare Airport-Rosemont, 5460 North River Road, Rosemont, IL 60018.

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, 301–496–0660, *benzingw@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 17, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18070 Filed 7–23–12; 8:45 am]

BILLING CODE 4140–01–P