

listing information, unless a waiver is granted.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Office of Critical Path Programs (HF-18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling the Office of Critical Path Programs at 301-827-1512. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Lonnie Smith, Office of Critical Path Programs (HF-18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-0011.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Requirements for drug establishment registration and drug listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) and 21 CFR part 207. Fundamental to FDA's mission to protect the public health is the collection of this information, which is used for important activities such as postmarket surveillance for serious adverse drug reactions, inspection of drug manufacturing and processing facilities, and monitoring of drug products imported into the United States. Comprehensive, accurate, and up-to-date information is critical to conducting these activities with efficiency and effectiveness.

Changes in the act, resulting from the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85), require that drug establishment registration and drug listing information be submitted electronically, unless a waiver is granted. Before FDAAA was enacted, section 510(p) of the act expressly provided that drug establishment registration information must be submitted electronically, based on a finding that electronic receipt was feasible, and section 510(j) of the act stipulated that drug listing information must be submitted in the form and

manner prescribed by FDA. Section 224 of FDAAA, which amends section 510(p) of the act, now expressly requires drug listing to be submitted by electronic means in addition to requiring electronic drug establishment registration.

Drug establishment registration and drug listing information have, until now, been submitted using a paper-based format, i.e., Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors). Moving from a paper-based format to an electronic system will improve the timeliness and accuracy of the submissions.

This guidance is designed to assist manufacturers, repackers, and relabelers with electronic submissions of drug establishment registrations and drug listing information. The guidance and accompanying technical documents explain (among other things):

- The statutory requirement to submit electronically drug establishment registration and drug listing information;
- How to create a Structured Product Labeling (SPL) file for submitting drug establishment registration and drug listing information to FDA through the Electronic Submissions Gateway (ESG) using defined code sets and codes, i.e., a language recognized by the computer system; and
- That FDA intends to no longer accept drug establishment registration and drug listing information in paper format, unless a waiver is granted. FDA encourages manufacturers, repackers, and relabelers to establish a gateway account as soon as possible so that they will be prepared to electronically submit drug establishment registration and drug listing information by June 1, 2009.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on providing regulatory submissions in electronic format for drug establishment registration and drug listing information. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic

comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection(s) of information in this guidance was approved under OMB control number 0910-0045.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/cvm/guidance/guidance.html>, and <http://www.regulations.gov>.

Dated: May 27, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-N-0664]

**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 August 4, 2009, from 8 a.m. to 5 p.m.

*Location:* Hilton Washington DC/Silver Spring, The Ballrooms, 8727

Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

**Contact Person:** Janie Kim, 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, email:

[Janie.kim@fda.hhs.gov](mailto:Janie.kim@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:** The committee will discuss bioequivalence recommendations for oral vancomycin hydrochloride capsule drug products.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and 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 July 21, 2009. 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 July 13, 2009. 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 July 14, 2009.

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 Janie Kim 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/oc/advisory/default.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: May 20, 2009.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

#### Dermatologic and Ophthalmic Drugs Advisory Committee; 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:** Dermatologic and Ophthalmic Drugs Advisory Committee.

**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 June 26, 2009, from 8 a.m. to 5 p.m.

**Location:** Hilton Washington DC/ Silver Spring, Maryland Ballrooms, 8727 Colesville Rd., Silver Spring, MD.

The hotel phone number is 301-589-5200.

**Contact Person:** Paul Tran, 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: 301-827-6778, e-mail: [paul.tran@fda.hhs.gov](mailto:paul.tran@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512534. 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:** The committee will discuss new drug applications (NDAs) 22-288, BEPREVE (bepotastine besilate) ophthalmic solution, 1.5%, ISTA Pharmaceuticals, Inc., proposed for the treatment of ocular itching associated with allergic conjunctivitis, and NDA 22-358, sodium hyaluronate ophthalmic solution, 0.18%, River Plate Biotechnology, Inc., proposed for the treatment of the signs and symptoms of dry eye disease.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and 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 June 17, 2009. Oral presentations from the public will be scheduled between approximately 9:30 a.m. to 10 a.m., and 1:30 p.m. to 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