

visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

**Contact Person:** Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [PADAC@fda.hhs.gov](mailto:PADAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss new drug application (NDA) 203108, for olodaterol (proposed trade name Striverdi Respimat) metered dose inhaler, sponsored by Boehringer Ingelheim, for the proposed indication of long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

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 meeting 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 January 14, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals

interested in making 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 January 4, 2013. 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 January 7, 2013.

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 Cindy Hong 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: November 15, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Pulmonary-Allergy 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:** Pulmonary-Allergy 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 January 30, 2013, from 8 a.m. to 4 p.m.

**Location:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

**Contact Person:** Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [PADAC@fda.hhs.gov](mailto:PADAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss the new drug application (NDA) 202049, for mannitol inhalation powder (proposed trade name BRONCHITOL), for oral inhalation sponsored by Pharmaxis, for the proposed indication of management of cystic fibrosis in patients aged 6 years and older to improve pulmonary function.

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 meeting 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 January 14, 2013. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 p.m. Those individuals interested in making 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 January 4, 2013. 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 January 7, 2013.

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

Dated: November 15, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0974]

#### Development of Prioritized Therapeutic Area Data Standards; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the intent to prioritize and develop therapeutic area data standards to facilitate the conduct of clinical research and the regulatory review of medical products. Therapeutic area disease and domain specific data standards should enable and enhance the ability to integrate, analyze, report, and share regulatory information. FDA has developed a roadmap that provides its current thinking on therapeutic area priorities and has posted it on the FDA Web site. FDA is actively participating with regulated industry, the Clinical Data Interchange Standards Consortium (CDISC), the Critical Path Institute, Health Level 7's (HL7) Clinical Interoperability Council, and other stakeholders to support the development of these therapeutic area standards. The therapeutic area standards will be developed collaboratively based on open, consensus-based data standards development methodology.

**DATES:** To ensure that the Agency considers your comments, submit either electronic or written comments by January 22, 2013.

**ADDRESSES:** Submit written requests for a copy of the roadmap to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on FDA's objective to develop prioritized therapeutic area data standards or on the roadmap to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the roadmap.

#### FOR FURTHER INFORMATION CONTACT:

Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1160, Silver Spring, MD 20993-0002, [CDERDataStandards@fda.hhs.gov](mailto:CDERDataStandards@fda.hhs.gov); or Amy Malla, Center for Biologics Evaluation and Research (HFM-25), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6085.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Traditionally, clinical study data submitted to FDA is in a format that is unique to each individual sponsor; furthermore the data quality varies. This has created inefficiencies in the review process and impeded efforts to analyze the data across applications when such analyses could be beneficial to detect trends in safety or efficacy or for other reasons. Sponsor adoption of available clinical trial data standards (CDISC/SDTM) for the submission of product applications have helped to improve the quality and standardization of submitted data. However, such a voluntary approach has proved insufficient to support both the current business requirements as well as efforts to modernize the review environment.

In 2011, the Center for Drug Evaluation and Research (CDER) identified a set of disease and therapeutic areas that could benefit from further standardization. These content area standards are primarily intended to support the efficient evaluation of medical products as noted previously in this document. Several factors were considered in the identification of these areas: (1) Areas of particular need, (2) areas with existing data standardization projects underway, and (3) areas with greater drug development pipeline activity. The initial prioritization was based on the number of active investigational new drug applications (or INDs) and input from review divisions, as well as from industry. The three tiers of priority were assembled into a roadmap and posted on the FDA Web site at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm>. The roadmap sets out a sequence of standardization efforts to achieve significant results by December 2017. CDER established a small grants program to fund projects that develop