Location: Hilton Washington DC/Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910, 301–589–5200. For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at *http://fda.yorkcast.com/webcast/Viewer/?peid=ca9ce867368c410999cde1d63208e9ef1d.*

Contact Person: Donald W. Jehn or Joanne Lipkind, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 October 25, 2011, the committee will meet in open session to hear and discuss CBER's review of scientific and medical literature concerning the use of non-standardized allergen extracts in the diagnosis and treatment of allergic disease. FDA is announcing the availability of this report entitled ''CBER's Report of Scientific and Medical Literature and Information on Non-Standardized Allergen Extracts in the Diagnosis and Treatment of Allergic Disease'' elsewhere in this issue of the **Federal Register**.

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 October 18, 2011. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 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 October 11, 2011. 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 October 11, 2011.

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 Donald W. Jehn or Joanne Lipkind 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: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24597 Filed 9–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0599]

Center for Biologics Evaluation and Research Report of Scientific and Medical Literature and Information on Non-Standardized Allergenic Extracts in the Diagnosis and Treatment of Allergic Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease. The report is provided in a data file entitled ''Center for Biologics Evaluation and Research Report of Scientific and Medical Literature and Information on Non-Standardized Allergenic Extracts in the Diagnosis and Treatment of Allergic Disease.'' FDA is making this report available to provide information and obtain comments from public and private stakeholders. FDA will also seek input on the report from the Allergenic Products Advisory Committee (APAC) at a meeting to be held on October 25, 2011. FDA has not made any regulatory decisions concerning the report or the products discussed in the scientific literature and information cited. FDA will review comments and other information it receives, as part of its continued oversight of regulated products.

DATES: Submit either electronic or written comments on the report by November 25, 2011.

ADDRESSES: Submit written requests for single copies of the report to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The data file may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the data file document.

Submit electronic comments on the report to *http://www.regulations.gov.* Submit written comments on the report to the Division of Dockets Management

(HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing the availability of its report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease. FDA is making this report available to provide information and obtain comment on the report from public and private stakeholders. FDA will also seek input on the report from APAC at a meeting to be held on October 25, 2011. A separate notice of the APAC meeting is published elsewhere in this issue of the **Federal Register**. This process will assist FDA in its continued oversight of regulated products.

II. Discussion

In 2004, FDA formed an internal committee to review available scientific and medical data on the safety and effectiveness of non-standardized allergenic extracts. FDA formed this committee to consider the previous evaluations performed by the external allergenics advisory review panels under 21 CFR 601.25 (Panel I or ''Original Panel'') and under 21 CFR 601.26 (Panel II or ''Reclassification Panel''). Reports of the Original and Reclassification Panels are available at *http://www.fda.gov/BiologicsBloodVaccines/Allergenics/ucm272115.htm.* The internal committee designed a data file to use in its review and to archive supporting data. The data file includes a report of information for each product, including a discussion of each product reviewed, and a list of reviewed literature associated with each product. FDA's approach to creating this data file was presented to APAC on April 7, 2005, and discussed again at the APAC meeting on September 13, 2006.

After receiving favorable feedback from the APAC on FDA's proposed methodology, FDA proceeded to collect the following information in order to facilitate its assessment of safety and effectiveness of non-standardized allergenic products.

A. Literature Reviewed by the Allergenics Advisory Review Panels

This includes literature reviewed by the Original Panel as part of its final report in 1981 and literature reviewed by the Reclassification Panel as part of its final report in 1983.

B. Data Concerning the Effectiveness and Safety of Non-Standardized Allergenic Products That Have Become Available Since 1972

This includes published literature, available manufacturer data, and data from other external sources. FDA accumulated these data from the following sources:

1. Published Literature From 1972 to the Present

This literature was acquired by searching for articles using a PubMed and/or Institute for Scientific Information (ISI) search engine (English-language literature articles only).

2. Publicly Available Manufacturer Data

These data were obtained by reviewing information published in the literature.

3. Medwatch Data Collected for Years 1987 to 2010

These data were evaluated for safety related product trends.

4. Data From Other External Sources

These data were obtained by performing a broad Internet search (*e.g.,* Google) to check for any additional safety or effectiveness data not captured in published articles found via PubMed or ISI.

FDA collected information from published scientific and medical literature and other data sources for each extract in order to identify those studies that used acceptable alternative testing methods. FDA also collected information from studies that:

- *Provided identifiable, specific and valid nomenclature for the source materials used in the preparation of the allergenic extracts in the studies.*
- *Were performed using aqueous based extracts prepared from specifically identified source materials with correct nomenclature.*
- *Described identifiable, specific, and valid study methods.*
- *Provided objective and evaluable data.*
- *For skin test data in the studies:*

Obtained positive skin tests in index cases by either skin prick or intradermal methods, demonstrated by:

- Wheal or erythema;
- Where appropriate, comparison to positive and negative control data in same study subjects.
- *For studies with cross reactivity data, demonstrated cross reactivity by:*
- ELISA or RAST inhibition;
- Western immunoblot; or
- Other valid immunochemical data.

In reviewing evidence of efficacy, FDA did not consider to be adequate ''random experience,'' or reports that lacked sufficient scientific detail for proper evaluation (such as imprecise nomenclature). FDA also did not consider to be adequate ''isolated case reports'' unless corroborated by the following: (1) Other case reports from independent authors, (2) well-described allergen challenge data, or (3) valid cross-reactivity data.

FDA is providing its report of the collected literature and other data in a data file that is currently available in PDF format on FDA's Web site at *http://www.fda.gov/downloads/BiologicsBloodVaccines/Allergenics/UCM271330.pdf.* FDA welcomes comments on the scientific and medical literature and information presented in the data file.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

IV. Electronic Access

Persons with access to the Internet may obtain the data file at *http://www.fda.gov/downloads/BiologicsBloodVaccines/Allergenics/UCM271330.pdf* or *http://www.regulations.gov.*

Dated: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24598 Filed 9–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0013]

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.