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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 25, 2012, the comment period for the notice on 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 that appeared in the Federal Register of September 26, 2011 (76 FR 59407). In the notice, FDA requested comments from public and private stakeholders on the report it 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." The Agency is taking this action in response to input it received from the Allergenic Products Advisory Committee (APAC) at a meeting held on October 25, 2011, to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments on the report by April 25, 2012.

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:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 26, 2011 (76 FR 59407), FDA published a notice with a 60-day comment period to request comments on 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. Comments on the report will allow FDA to fully evaluate the information contained in the report.

The Agency received comments in the APAC meeting held on October 25, 2011, that FDA should consider extending the comment period for the notice for several months. Members

of the APAC expressed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice on FDA's report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease. Materials related to the report were discussed at this meeting and are available at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/AllergenicProductsAdvisoryCommittee/ucm247212.htm. When it is completed, a transcript of the meeting will also be available at this Web page.

FDA has considered the comments from the APAC meeting and is extending the comment period for the notice until April 25, 2012. The Agency believes that an extension until April 25, 2012, allows adequate time for interested persons to submit comments without significantly delaying the evaluation of these important issues.

FDA welcomes comments regarding 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. In particular, FDA is interested in additional data regarding the use of these extracts that had been previously published in the medical or scientific literature. Unpublished data should include the following information, if available: Date(s) of collection; extract(s) studied and method of preparation; dose and route of administration; patient demography; and additional clinical information (including confirmatory testing, such as challenges or serum specific IgE determinations).

II. Request for 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.

Dated: November 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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