4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0599]

Allergy Laboratories, Inc., Opportunity for Hearing on Proposal to Revoke U.S. License No. 103

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the biologics license (U.S. License No. 103) issued to Allergy Laboratories, Inc. for the manufacture of nonstandardized allergenic extract Dust, House Mixture. The proposed revocation is based on available scientific and medical information that does not support the safety and effectiveness of this nonstandardized allergenic extract.

DATES: Allergy Laboratories, Inc., may submit electronic or written requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], and any data and information justifying a hearing by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Other interested persons may submit electronic or written comments on the proposed revocation by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic requests for a hearing and any data and information justifying a hearing, or comments to http://www.regulations.gov. Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7252, Silver Spring, MD 20992-0002, 240-402-8105.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the biologics license (U.S. License No. 103) issued to Allergy Laboratories, Inc., 1005 SW 2nd St., Oklahoma City, OK 73109, for the manufacture of nonstandardized allergenic extract Dust, House Mixture. The proposed revocation is being initiated because FDA has concluded that nonstandardized allergenic extract Dust, House Mixture is not safe and effective for all of its intended uses or is misbranded with respect to any such use.

FDA recently conducted a comprehensive review of the published literature, available manufacturer data, and data from other external sources in order to assess the safety and effectiveness of nonstandardized allergenic extracts. FDA's review identified 17 nonstandardized allergenic extracts that raised potential safety issues, in addition to issues regarding inadequate evidence of their efficacy. FDA presented its findings to the public and to the Allergenic Product Advisory Committee (Advisory Committee) in September and October 2011, and received comments on the findings both at the Advisory Committee meeting and to the public docket that remained open through April 25, 2012. FDA received no evidence in support of any of the 17 specific nonstandardized allergenic extracts, either at the Advisory Committee meeting or to the docket. These 17 extracts were produced by a variety of manufacturers; however, 6 of the 17 extracts were listed in Allergy Laboratories, Inc.'s biologics license.

In a letter dated March 15, 2013, FDA notified Allergy Laboratories, Inc. that FDA intended to institute proceedings to revoke the biologics license issued to Allergy Laboratories, Inc. with regard to six nonstandardized allergenic extracts. FDA advised Allergy Laboratories,

Inc. that the six nonstandardized allergenic extracts are not safe and effective for all of their intended uses or are misbranded with respect to any such use. The letter also provided Allergy Laboratories, Inc. with a reasonable period of time to provide data that had not been considered and reviewed by FDA, and an opportunity for a hearing under § 12.21(b) (21 CFR 12.21(b)).

In a letter dated March 25, 2013, Allergy Laboratories, Inc. informed FDA that the manufacturer intended to provide additional detailed data not previously considered by FDA regarding the safety and effectiveness of the remaining nonstandardized allergenic extract Dust, House Mixture. On April 12, 2013, Allergy Laboratories, Inc. submitted information regarding Dust, House Mixture. FDA reviewed the information provided by Allergy Laboratories, Inc. and in a letter dated June 12, 2013, advised Allergy Laboratories, Inc. that the manufacturer had failed to provide additional information or data that had not previously been considered and reviewed by FDA.

In accordance with § 601.5(b) (21 CFR 601.5(b)), in the June 12, 2013, letter, FDA advised Allergy Laboratories, Inc. that FDA would institute proceedings to revoke Allergy Laboratories, Inc.'s U.S. License No. 103, with regard to nonstandardized allergenic extract Dust, House Mixture. FDA offered Allergy Laboratories, Inc., the option to voluntarily request that the license for nonstandardized allergenic extract Dust, House Mixture be revoked. In the June 12, 2013, letter, FDA further advised Allergy Laboratories, Inc. that if it failed to voluntarily request that the license be revoked, FDA would initiate proceedings to revoke the license with regard to nonstandardized allergenic extract Dust, House Mixture, by publishing in the Federal Register a notice of opportunity for a hearing on a proposal to revoke the license under § 12.21(b), as provided in § 601.5(b). Allergy Laboratories, Inc. did not respond to FDA's letter within the specified response period.

In accordance with §§ 601.5(b) and 12.21(b), FDA is issuing a notice of opportunity for a hearing on a proposal to revoke the U.S. License No. 103, of Allergy Laboratories, Inc. with regard to nonstandardized allergenic extract Dust, House Mixture.

FDA has placed copies of letters between FDA and Allergy Laboratories, Inc. relevant to the proposed revocation on file, with the Division of Dockets Management (see ADDRESSES) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) March 15, 2013, letter from FDA to Allergy Laboratories, Inc. providing notice of the intent to institute proceedings to revoke its biologics license with regard to six specific nonstandardized allergenic extracts that raised specific safety concerns; (2) April 12, 2013, response letter from Allergy Laboratories, Inc. to FDA; and (3) June 12, 2013, letter from FDA to Allergy Laboratories, Inc. These documents are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Allergy Laboratories, Inc. may submit an electronic or written request for a hearing to the Division of Dockets Management [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], and any data and information justifying a hearing must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Other interested persons may submit comments on the proposed license revocation to the Division of Dockets Management by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation (§ 12.22(b)).

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest on mere allegations or denials, but must set forth a genuine and substantial issue of fact that requires a hearing (§ 12.24(b)). If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

Only one copy of any submission need be provided to FDA. Submissions are to be identified with the docket number found in brackets in the heading of this document. Submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be examined in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to Commissioner of Food and Drugs and redelegated to the Director and Deputy Director of the Center for Biologics Evaluation and Research (FDA Staff Manual Guide 1410.203).

Dated: April 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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