TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 361.1(c)(2) | 69 | 4 | 276 | 10 | 2,760 |
| 361.1(d)(5) | 35 | 18 | 630 | [2] 0.75 | 472.5 |
| Total | | | | | 3,232.5 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 45 minutes.

Dated: April 21, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–09773 Filed 4–29–14; 8:45 am]

**BILLING CODE 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 May 30, 2014, and any data and information justifying a hearing by June 30, 2014. Other interested persons may submit electronic or written comments on the proposed revocation by June 30, 2014.

**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 May 30, 2014, and any data and information justifying a hearing must be submitted by June 30, 2014 . Other interested persons may submit comments on the proposed license revocation to the Division of Dockets Management byJune 30, 2014. 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.*

[FR Doc. 2014–09771 Filed 4–29–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2012–E–0036; FDA–2012–E–0149; FDA–2012–E–0150; and FDA–2012–E–0151]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; BRILINTA

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for BRILINTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product BRILINTA (ticagrelor). BRILINTA is indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for BRILINTA (U.S. Patent Nos. 6,525,060; 6,251,910; 7,250,419; and 7,265,124) from AstraZeneca UK Limited, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated