DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0383]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 30, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0053. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Radioactive Drug Research Committees—(OMB Control Number 0910–0053)—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic scientific research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees (RDRC) and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved RDRC (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each RDRC shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the RDRC, using Form FDA 2914, and a summary of each study conducted during the preceding year, using Form FDA 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the RDRC all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks.

Respondents to this information collection are the chairperson(s) of each individual RDRC, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations.

In the **Federal Register** of January 27, 2014 (79 FR 4348), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Sections/Forms	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
361.1(c)(3) & (4); Form FDA 2914	69	1	69	1	69
361.1(c)(3); Form FDA 2915	48	10	480	3.5	1,680
361.1(d)(8)	10	5	50	[2] 0.5	25
Total					1,774

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

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