

requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft plan.

Submit electronic comments on the draft plan to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Cheryl Ford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6737, [UserFeesProgram-Informatics@fda.hhs.gov](mailto:UserFeesProgram-Informatics@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The draft PDUFA V IT plan considers assumptions, available resources, and statutory requirements that conform to the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012. Section 1136 of FDASIA, Electronic Submission of Applications, gives FDA the authority to require a standardized electronic format for the submission of information and data in standardized formats. Section 1136 addresses investigational new drug applications, biologics license applications, and new drug applications under the PDUFA program as well as abbreviated new drug applications under the Generic Drug User Fee Act program and describes new standards and processes affecting drug and biologics approvals, drug supply chain, and other topics related to human pharmaceuticals. The draft PDUFA V IT plan describes key activities for enabling progress toward achieving PDUFA IT goals.

**II. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ForIndustry/UserFees/default.htm> or <http://www.regulations.gov>.

Dated: December 20, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-30818 Filed 12-24-13; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Allergenic Products Advisory Committee; Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Allergenic Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 28, 2014, between approximately 8:30 a.m. and 3:30 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at: <https://collaboration.fda.gov/apac>.

*Contact Person:* Gail Dapolito 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). 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 at <http://www.fda.gov/AdvisoryCommittees/>

[default.htm](#) and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On January 28, 2014, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of RAGWITEK, a short ragweed pollen allergen extract tablet for sublingual use, manufactured by Merck, indicated for immunotherapy for diagnosed ragweed pollen induced allergic rhinitis, with or without conjunctivitis.

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 meeting 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 January 21, 2014. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on January 28, 2014. 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 January 13, 2014. 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 January 14, 2014.

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 Gail Dapolito 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: December 20, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-30799 Filed 12-24-13; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request: Early Career Reviewer Program Online Application System—Center for Scientific Review (CSR)**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork

Reduction Act of 1995, the Center for Scientific Review, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 13, 2013, page 15959 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number

*Proposed Collection:* Early Career Reviewer Program Online Application System—Existing collection in use without an OMB number—Center for Scientific Review (CSR), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. Our mission is to see that NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research. To accomplish this

goal, Scientific Review Officers (SRO) form study sections consisting of scientists who have the technical and scientific expertise to evaluate the merit of grant applications. The CSR Early Career Reviewer (ECR) program was developed to identify and train qualified scientists who are early in their scientific careers and who have not had prior CSR review experience. Currently, the application process involves repeated email interactions with potential applicants and manual management of information. To make the application process more efficient for applicants and for CSR staff, we have collaborated with the Information Management Branch at CSR to develop online application software which includes the collection of applicants' names, contact information, and professional CVs. This PRA clearance request is to deploy the online application software for ECR program applicants—the Early Career Reviewer Application and Vetting System (EAVS).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 650.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Type of respondent | Number of respondents | Number of responses per respondent | Average time per response ( in hours) | Total annual burden hour |
|--------------------|-----------------------|------------------------------------|---------------------------------------|--------------------------|
| Applicants .....   | 1,560                 | 1                                  | 25/60                                 | 650                      |

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs,

*OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Monica Basco, ECR Program Coordinator, Center for Scientific Review, 6701 Rockledge Dr., Room 3220, Bethesda, MD 20892 or call non-toll-free number (301) 300-3839 or

Email your request, including your address to:

*CSREarlyCareerReviewer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: December 17, 2013

**Timothy J. Tosten,**

*Executive Officer, Deputy Ethics Counselor, Director, Division of Management Services, Center for Scientific Review, NIH.*

[FR Doc. 2013-30817 Filed 12-24-13; 8:45 am]

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