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.
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

<table>
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<tr>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average time per response (in hours)</th>
<th>Total annual burden hour</th>
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<td>25/60</td>
<td>650</td>
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</table>

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]
BILLING CODE 4140–01–P