reductions in user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 21 U.S.C. 379h) (the FD&C Act). The guidance describes the types of waivers and reductions permitted under the user fee provisions of the FD&C Act, and the procedures for submitting requests for waivers or reductions. It also includes recommendations for submitting information for requests for reconsideration of denials of waiver or reduction requests, and for requests for appeals. The guidance also provides clarification on related issues such as user fee exemptions for orphan drugs.

We estimate that the total annual number of waiver requests submitted for all of these categories will be 120, submitted by 100 different sponsors. We estimate that the average burden hours for preparation of a submission will total 16 hours. Because FDA may request additional information from the applicant during the review period, we have also included in this estimate time to prepare any additional information.

The reconsideration and appeal requests are not addressed in the FD&C Act but are discussed in the guidance. We estimate that we will receive 3 requests for reconsideration annually, and that the total average burden hours for a reconsideration request will be 24 hours. We estimate that we will receive 1 request annually for an appeal of a user fee waiver determination, and that the time needed to prepare an appeal would be approximately 12 hours. We have included in this estimate both the time needed to prepare the request for appeal and the time needed to create and send a copy of the request for an appeal to the Associate Director for Policy at the Center for Drug Evaluation and Research.

The burden for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) has not been included in the burden analysis, because that information collection is already approved under OMB control number 0910–0297. The collections of information associated with a new drug application or biologics license application have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

We have included in the burden estimate the preparation and submission of application fee waivers for small businesses, because small businesses requesting a waiver must submit documentation to FDA on the number of their employees and must include the information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval. Because the Small Business Administration (SBA) makes the size determinations for FDA, small businesses must also submit information to the SBA. The submission of information to SBA is already approved under OMB control number 3245–0101.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

User fee waivers, reductions, and refunds for drug and biological products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FD&C Act sections 735 and 736	100	1.2	120	16	1,920
Reconsideration Requests	3	1	3	24	72
Appeal Requests	1	1	1	12	12
Total					2,004

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

Dated: February 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04688 Filed 3–3–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Institutional Review Boards

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 April 3, 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 0910–0130. 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.

Institutional Review Boards—21 CFR 56.115—(OMB Control Number 0910–0130)—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (IRBs) are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: (1) Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; (2) the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; (3) minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; (4) records of continuing

review activities; copies of all correspondence between investigators and the IRB; (5) statement of significant new findings provided to subjects of the research; and (6) a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 2,500 IRBs. The IRBs meet on an average of 14.6 times annually. The Agency estimates that approximately 100 hours of person-time per meeting are required to meet the requirements of the regulation.

In the **Federal Register** of October 1, 2013 (78 FR 60286), 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 RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
56.115	2,500	14.6	36,500	100	3,650,000

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

Dated: February 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04707 Filed 3–3–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Assessment of DAIDS Training Resources

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Jacquelyn Burns, Office for Policy in Clinical Research Operations, DAIDS, NIAID, 6700B Rockledge Drive, Room 4118, Bethesda, MD 20852, or call non-toll-free number 301–402–0143, or Email your request, including your address to: *Jburns@niaid.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 60 days of the date of this publication.

Proposed Collection: Assessment of DAIDS Training Resources, 0925-New, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a new data collection in order to assess the efficacy of training resources and their impact on NIAID-supported and/or sponsored research operations. The generic OMB clearance will allow collecting information about the knowledge, attitudes, and behaviors from target audiences (e.g., research staff) to help improve and inform these training resources. Information collected will be used to determine the future direction for training resources, including which resources should be continued, enhanced, added, or discontinued in order to utilize resources efficiently.

Findings will provide data to inform and guide the optimal development, dissemination, and revisions to improve NIAID trainings and resources. Various types of data will be collected, including post-assessment tests, questionnaires, interviews, and focus groups. Post-assessment tests will be administered at the time of the trainings to assess trainees' immediate knowledge gained, as well as reactions and satisfaction to the content. Select trainees will be queried at later time points (e.g., three-months, six-months) after they have participated in a training to understand if they have been able to apply their knowledge at the workplace, and identify facilitators or hindrances to implementing this new knowledge. The assessment team will conduct repeated data collections for these select trainees to determine any changes throughout time. In order to obtain information beyond self-reported data, select managers and supervisors will also be queried to assess if they have observed any changes in their staff after attending trainings, and if the work environment is conducive for trainees to implement knowledge from trainings.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 847.