cannot be measured from claims data or other sources. We will use brief, standardized scales with demonstrated reliability and validity in older adults. Information collected in the survey is not of a sensitive nature. Questions in the beneficiary survey are confined to health outcomes. RTI International will conduct and analyze the survey. RTI has experience doing similar work for ASPE and other government clients.

Need and Proposed Use of the Information: To determine the impact of the SASH program on quality of life, health and functional status of participants. Care has been taken to ensure that there is no overlap between other ongoing state evaluations. Through discussions with SASH program staff and other state officials in Vermont, we determined that the information we seek to collect is not already being collected from our proposed sample, nor can it be measured from claims data. As a result of these efforts, the information collected through the survey will not duplicate any other effort and is not obtainable from any other source.

Likely Respondents: The target population for the survey is Medicare beneficiaries participating in the Support and Services at Home (SASH) demonstration. SASH provides integrated, home-based services to beneficiaries in selected housing properties throughout Vermont. At this point, 1,685 intervention beneficiaries have been identified in 37 SASH sites.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
SASH Participant Survey	669	1	20/60	223
Total	669	1	20/60	223

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2014–04755 Filed 3–3–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0222]

Agency Information Collection Activities: Proposed Collection; Comment Request; User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recommendations to applicants considering whether to request a waiver or reduction in user fees.

DATES: Submit either electronic or written comments on the collection of information by May 5, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

User Fee Waivers, Reductions, and Refunds for Drug and Biological Products (OMB Control Number 0910–0693)—Extension

The guidance provides recommendations for applicants planning to request waivers or

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]

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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