Reductions in data elements are found throughout the data collection but are concentrated in the consumer demographic components. Due to the aggregate level nature of the SPR, information on combinations of demographic characteristics (*e.g.,* number of women served who are 65 years or older and have 2 activity of daily living limitations) require exponentially larger numbers of data elements compared to single demographic characteristics (*e.g.* number of women served). To reduce the reporting burden associated with the number of data elements ACL is proposing to limit data element combinations. For example, the revised SPR asks for demographic characteristic such as age, race, and gender for three or more ADL and IADLs rather than for zero, one, two and three or more ADLs and IADLs. The remaining proposed demographic data elements include indicators of priority populations (*i.e.,* social and economic vulnerability and frailty) found in the OAA and will allow ACL to continue to measure efforts to target services.

Limited expansions in data elements are found in the Title III–E National Family Caregiver Support Program service component. The proposal separates out three service areas that were reported as a whole (*i.e.,* counseling, training and support group services). Separation allows for support group services to be categorized as a non-registered service for which consumer demographic details are no longer reported. Additional information regarding the types of respite services provided under the OAA is sought. The proposal separates assistance services into two types: (1) Case management, and (2) information and assistance. Case management assistance services are categorized as registered, meaning caregiver demographic data are reported while information and assistance services do not include reporting of demographic data. Supplemental services are reported in the same manner as ''other service'' under Title III–B, Home and Community-based Services (HCBS) program. Across the OAA services, greater detail regarding expenditure data is proposed. Under Title III–B, HCBS program, the proposed data collection expands data regarding Title VII legal assistance services. The ACL seeks data on the OAA identified priority legal issues for closed cases.

Comments in Response to the 60-Day *Federal Register* Notice

A 60-day **Federal Register** Notice was published in the **Federal Register** on June 1, 2017, Vol. 82, No. 104, pp. 25293–25294.

ACL received comments from fourteen (14) organizations and one (1) individual about the State Performance Report (SPR) redesign. ACL reviewed all of the comments, but some of the comments were deemed not relevant because they were: (a) About the data submission process itself (b) did not request a change (c) only commented on the format (d) indicated topics for technical assistance and training for the final data collection or (e) provided commentary without referencing the SPR. Regarding concerns about the:

- Timeline-ACL proposes moving the effective date back by 12 months,
- Cost, burden, and changes to data elements-ACL recognizes that there is always a cost to changing data systems, but believes that the anticipated improvement in the data justifies the proposed changes,
- New items related to Legal Services-ACL worked closely with program staff and stakeholders to develop a reasonable data collection to measure the contribution of this important program about which performance data were not previously collected,
- Need for additional elements including sub-state and individual level data-ACL is not adding more elements or more granular data collection at this time but will consider those suggestions for future data collections,
- Need for improved definitions and language-ACL made several changes to specific elements and is using these comments to inform the training and technical assistance it provides, and
- Caregiver program-ACL made revisions to several items and is using these comments to inform the training and technical assistance it provides.

A detailed analysis of the comments and responses can be found at (*https://www.reginfo.gov/public/do/PRAMain.*

The proposed data collection template may be found on the ACL website at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows: 56 State Agencies on Aging respond annually and it will take an average of 33.5 hours for a total of 1,876 hours. This is a reduction of 874 hours from the previous version. The burden estimate of 33.5 hours was derived from feedback from grantees.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Older American Act Title III and Title VII (Chapters 3 and 4) Annual State Program Reporting	56	1	33.5	1,876
Total	56	1	33.5	1,876

Dated: March 26, 2018.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2018–06662 Filed 3–30–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1010]

Food and Drug Administration Prescription Drug User Fee Act VI Benefit-Risk Implementation Plan; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft 5-year plan describing the Agency's approach to further the implementation of structured benefit-risk assessment, including the incorporation of the patient's voice in drug development and decision-making, in the human drug review program and the opportunity for public comment on the draft plan. This new draft plan is an update to the 5-year plan published in February 2013 on FDA's website. This new draft plan is

part of FDA's commitments that were made as part of the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). FDA has published the draft plan on its website.

DATES: Submit either electronic or written comments by June 1, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 1, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–1010 for ''Food and Drug Administration Prescription Drug User Fee Act VI Benefit-Risk Implementation Plan; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 5-year plan describing the Agency's approach to further the implementation of structured benefit-risk assessment into human drug and biologics review. This draft plan is intended to meet a performance goal included in the sixth authorization of PDUFA (PDUFA VI). This reauthorization, part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.*

This new draft plan is an update to the 5-year plan published in February 2013 on FDA's website: *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf.*

FDA's commitments to meet certain performance goals under PDUFA VI were developed in consultation with patient and consumer advocates, health care professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.2 of the commitment letter, ''Enhancing Benefit-Risk Assessment in Regulatory Decision-Making'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*) outlines FDA's commitments in this area, including publication of an update to the implementation plan published in 2013 entitled ''Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf*). The update includes a report on the progress made during PDUFA V and a plan for continued implementation during Fiscal Years (FY) 2018–2022. The publication and implementation of this plan are intended to fulfill the commitments described in Section J of the PDUFA VI Commitment Letter.

II. FDA Draft PDUFA VI Benefit-Risk Implementation Plan

Benefit-risk assessment is the foundation for FDA's regulatory review of human drugs and biologics. In PDUFA V, FDA's Center for Drug

Evaluation and Research and Center for Biologics and Research committed to further our efforts to enhance benefit-risk assessment and communication in the human drug review process in FY 2013–2017. Enhancing and communicating benefit-risk assessment continues to be an Agency priority in PDUFA VI. The draft plan describes the progress made on PDUFA V in benefit-risk assessment. This progress includes revision of FDA's review/decision templates and manuals to incorporate FDA's approach to benefit-risk assessment, training review and management of staff on the revised templates and manuals, developing an evaluation plan to ascertain the impact of FDA's implementation of the Benefit-Risk Framework in drug review, holding two public workshops on benefit-risk considerations from the regulator's perspective, and advancing FDA's Patient-Focused Drug Development initiative. This draft plan also summarizes the third-party evaluation of FDA's implementation of the Benefit-Risk Framework into FDA's new drug review.

The plan also includes an overview of FDA's commitments in PDUFA VI for continued implementation of structured benefit-risk assessment during FY 2018–2022. These commitments include participating in a meeting to gather stakeholder input on key topics, publishing a draft guidance on benefit-risk assessment for new drugs and biologics, continuing to revise relevant Manuals for Policies and Procedures and Standard Operating Practices and Procedures to incorporate benefit-risk assessment approaches, and conducting a second evaluation of the implementation of the Benefit-Risk Framework beginning in 2021. In addition to these commitments, FDA also plans to explore additional opportunities to enhance our use and communication of benefit-risk assessments.

III. Electronic Access

FDA has published the draft plan on its website: *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.* The period for public comment on the draft plan will remain open for 60 days following the publication of this notice. After consideration of public comments, FDA will finalize the plan. Throughout PDUFA VI, the Agency will update the plan as necessary and post all updates on FDA's website.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06531 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0369]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 the reporting and recordkeeping requirements of our regulations implementing the Federal Import Milk Act (FIMA).

DATES: Submit either electronic or written comments on the collection of information by June 1, 2018.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 1, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–N–0369 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations under the Federal Import Milk Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available