the Agency under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act who requests formal resolution of a scientific or procedural dispute.

Burden Estimate: Provided in this document is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately eight sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately one respondent submits requests for formal dispute resolution to CBER annually. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 31 requests annually and CBER receives approximately 1 request annually. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the Agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 8 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Requests for formal dispute resolution	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER	8	2	31	8	248
CBER	1	1	1	8	8
Total					256

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

Dated: May 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13386 Filed 6–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0748]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Generic Drug User Fee Cover Sheet; Form FDA 3794

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 concerning collection of information using Form FDA 3794 entitled ''Generic Drug User Fee Cover Sheet.''

DATES: Submit either electronic or written comments on the collection of information by August 3, 2015.

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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Generic Drug User Fee Cover Sheet; Form FDA 3794

OMB Control Number 0910–0727—Extension

On July 9, 2012, the Generic Drug User Fee Act (GDUFA) (Pub. L. 112–144, Title 111) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug manufacturers pay user fees to finance critical and measurable program enhancements. The user fees required

by GDUFA are as follows: A one-time fee for original abbreviated new drug applications (ANDAs) pending on October 1, 2012 (also known as backlog applications); fees for type II active pharmaceutical ingredient (API) and final dosage form (FDF) facilities; fees for new ANDAs and prior approval supplements (PASs); and a one-time fee for drug master files (DMFs).

The purpose of this notice is to solicit feedback on the collection of information in an electronic form used to calculate and pay generic drug user fees. Proposed Form FDA 3794, the Generic Drug User Fee Cover Sheet, requests the minimum necessary information to determine if a person has satisfied all relevant user fee obligations. The proposed form is modeled on other FDA user fee cover sheets, including Form FDA 3397, the Prescription Drug User Fee Act Cover Sheet. The information collected would be used by FDA to initiate the administrative screening of generic drug submissions and DMFs, support the inspection of generic drug facilities, and otherwise support the generic drug program. A copy of the proposed form will be available in the docket for this notice.

Respondents to this proposed collection of information would be potential or actual generic application holders and/or related manufacturers (manufacturers of FDF and/or APIs). Companies with multiple applications will submit a cover sheet for each application and facility. Based on FDA's database of application holders and related manufacturers, we estimate that approximately 460 companies would submit a total of 3,544 cover sheets annually to pay for application and facility user fees. FDA estimates that the 3,544 annual cover sheet responses would break down as follows: 1,439 facilities fees, 942 ANDAs, 502 PASs, and 661 Type II API DMFs. The estimated hours per response are based on FDA's past experience with other submissions and range from approximately 0.1 to 0.5 hours. The hours per response are estimated at the upper end of the range to be conservative.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794	460	7.7	3,544	0.5 (30 min.)	1,772

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

Dated: May 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13352 Filed 6–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement of Organization, Functions, and Delegations of Authority; Administration for Community Living

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) was created in order to achieve several important objectives: to reduce the fragmentation that currently exists in federal programs addressing the community living service and support needs of both the aging and disability populations; to enhance access to quality health care and long-term services and supports for older adults and people with disabilities; to promote consistency in community living policy across other areas of the federal government; and to complement the community infrastructure, as supported by both Medicaid and other federal programs, in order to better respond to the full spectrum of needs of seniors and persons with disabilities. Public Law 113–128, the Workforce Innovation and Opportunity Act (WIOA), furthers these objectives by transferring three groups of programs—the Independent Living (IL) Programs, the National Institute on Disability and Rehabilitation Research (now titled the National Institute on Disability, Independent Living, and Rehabilitation Research), and the Assistive Technology (AT) Act programs—from the Department of Education's Office of Special Education and Rehabilitative Services (OSERS) to the HHS Administration for Community Living (ACL). This reorganization incorporates these programs into ACL's structure with the IL programs and the AT Act section 5 programs included under the newly established Administration on Disabilities; the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) reporting directly to the ACL Administrator; and the AT Act section 4 programs located in the Office of Consumer Access and Self-Determination within the renamed Center for Integrated Programs (formally the Center for Consumer Access and Self-Determination).

FOR FURTHER INFORMATION CONTACT: Christine Phillips, Administration for Community Living, 1 Massachusetts Avenue NW., Washington, DC 20201, 202–357–3547.

SUPPLEMENTARY INFORMATION: This notice amends part B of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Community Living, as last amended at 79 FR 62142–62152, dated October 16, 2014, as follows:

I. Delete Part B, ''The Administration for Community Living''; in its entirety and replace with the following:

B.00 Mission
B.10 Organization
B.20 Functions

B.00 Mission. The Administration for Community Living's (ACL) mission is to maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers. ACL provides national leadership and direction to plan, manage, develop, and raise awareness of comprehensive and coordinated systems of long-term services and supports that enable older Americans and individuals with disabilities, including intellectual, developmental, physical, and other disabilities, to maintain their health and independence in their homes and communities. ACL programs support strong state, tribal, and local community networks designed to respond to the needs of persons with disabilities, older Americans, and their families through advocacy, research, systems change and capacity building to ensure access to needed community services,