

regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates that an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are

accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that it will take clinical investigators 15 minutes to submit such records to the sponsor.

Subsequent to publication of the 60-day notice, FDA reestimated the information collection. Upon additional

inspection of the data, FDA has updated the estimated recordkeeping burden hours to more accurately reflect the burden.

In the **Federal Register** of March 28, 2012 (77 FR 18826), 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 REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (a)(2)—Form FDA 3454 .....	902	1	902	1	902
Disclosure—54.4(a)(3)—Form FDA 3455 .....	90	1	90	5	450
Total .....					1,352

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping—54.6 .....	902	1	902	0.25	226

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Clinical Investigators—54.4(b) .....	10,554	1	10,554	0.17	1,794

Dated: July 16, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0748]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; 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 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 September 24, 2012.

**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:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, [juanmanuel.vilela@fda.hhs.gov](mailto:juanmanuel.vilela@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 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—New)**

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 the 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 500 companies would submit a total of 3,850 coversheets annually to pay for application and facility user fees. FDA estimates that the 3,850 annual cover sheet responses would break down as follows: <sup>1</sup> 2,000 facilities fees, 750 ANDAs, 750 PASs, and 350 Type II API DMFs. We also estimate that the one-time backlog fee would affect 350 application owners sponsoring 2,700 applications. 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 <sup>1</sup>**

Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794 <sup>2</sup> .....	500	7.7	3,850	0.5	1,925

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> For all applicable applications and fees except for the backlog fee.

The backlog fee is a one-time fee. The Agency expects the majority of these

fees to be received in the first year only. The estimated reporting burden for the

backlog fee is shown in table 2 of this document.

**TABLE 2—ESTIMATED ONE-TIME ANNUAL REPORTING BURDEN <sup>1</sup>**

Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794 <sup>2</sup> .....	350	7.7	2,700	0.5	1,350

<sup>1</sup> There are no capital costs or operating maintenance costs associated with this collection of information.

<sup>2</sup> For backlog fee.

<sup>1</sup> These estimates are based on conversations between the Agency and representatives of

regulated industry during the generic drug user fee negotiations.

Dated: July 18, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-18232 Filed 7-25-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Food and Drug Administration Pediatric Medical Devices Workshop; Notice of Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following workshop: FDA Pediatric Medical Devices Workshop. This meeting is intended to focus on challenges in pediatric device development—namely, business planning and funding concerns; and how sponsors can most effectively interact with the FDA. The goal of this meeting is to engage and educate pediatric innovators and device industry sponsors.

This educational meeting will consist of live presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. The interactive meeting will also include a “mock” FDA pre-submission meeting for a “mock” pediatric medical device, to illustrate how such encounters may transpire. In addition, attendees will have an opportunity during lunch to engage with Pediatric Device Consortia Grant Program leaders. The meeting will be recorded for subsequent posting on the FDA Web site.

**Date and Time:** The meeting will be held on September 24, 2012, from 8 a.m. to 5:30 p.m.

**Location:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. For participants who cannot attend the live meeting, a recorded Web cast will be made available after the meeting.

**Contact:** Linda Ulrich, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5206, Silver Spring, MD 20993-0002, 301-796-8686, FAX: 301-847-8621, email: [megan.mcnamee@icfi.com](mailto:megan.mcnamee@icfi.com).

**Registration:** Interested participants may register for this meeting at the following Web site: [https://events-](https://events-support.com/events/FDA_OOPD_Pediatric_Medical_Devices_Workshop)

[support.com/events/FDA\\_OOPD\\_Pediatric\\_Medical\\_Devices\\_Workshop](https://events-support.com/events/FDA_OOPD_Pediatric_Medical_Devices_Workshop). Please note that registration for the live meeting will be limited based on available seating.

If you need sign language interpretation during this meeting, please contact Linda Ulrich at: [Linda.Ulrich@fda.hhs.gov](mailto:Linda.Ulrich@fda.hhs.gov) by August 24, 2012.

The FDA Pediatric Medical Devices Workshop is supported by FDA's Office of Orphan Product Development and will include participants from the FDA's Center for Devices and Radiologic Health.

(FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: July 17, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Draft Policy on Conferring With Urban Indian Organizations

**AGENCY:** Indian Health Service, Department of Health and Human Services.

**ACTION:** Notice, with a 45-day comment period.

**SUMMARY:** This Notice sets forth the Indian Health Service policy for conferring with urban Indian organizations and invites comments within 45 days. In March 2010, the Indian Health Care Improvement Act was reauthorized and amended as part of the Patient Protection and Affordable Care Act, Public Law 111-148, as amended by the Health Care and Education Reconciliation Act (together, the Affordable Care Act), Public Law 111-152. One of the changes made to the IHCA was to create a new requirement that the IHS “confer” with UIOs, to the maximum extent practicable, in carrying out the Act as defined by the Indian Health Care Improvement Reauthorization and Extension Act, as enacted and amended by the Affordable Care Act.

**DATES:** We will consider all comments received by September 10, 2012.

**ADDRESSES:** Submit comments by email to [Betty.Gould@ihs.gov](mailto:Betty.Gould@ihs.gov); or by US mail to: Ms. Betty Gould, Regulations Officer,

Indian Health Service, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ms. Phyllis Wolfe, Director, Office of Urban Indian Health Programs, Indian Health Service, 801 Thompson Avenue, Suite 200, Rockville, Maryland 20852. Telephone 301/443-4680 (This is not a toll free number).

#### Policy on Conferring With Urban Indian Organizations

##### 5-26.1 Introduction

**A. Purpose.** Congress has specifically declared that it is the policy of the Nation “to ensure the highest possible health status for Indians and urban Indians.” 25 U.S.C. 1602(1). The U. S. Department of Health and Human Services (HHS) is committed to working with Indian and urban Indian communities to meet this policy. This policy applies to the Indian Health Service (IHS).

This Notice establishes the IHS policy and procedures for conferring with urban Indian organizations (UIOs). The IHS will use this conferring policy to ensure that the health care needs of the urban Indian population are considered at the local, Area, and national levels, when implementing and carrying out the Indian Health Care Improvement Act (IHCA).

**B. Background.** Urban Indian organizations are a major provider of health care to urban American Indians and Alaska Natives (AI/AN) across the country. When the IHCA was enacted into law in 1976, it identified the authorities, responsibilities, and functions of the IHS, the primary Federal Agency charged with providing health care to AI/AN. The IHCA included the authority for the IHS to “establish programs in urban centers to make health services more accessible to urban Indians” [Indian Health Care Improvement Act, Title V, section 501, Pub. L. 94-437, 90 Statute (Stat.) 1400, 1410 (1976), codified at 25 United States Code (U.S.C.) 1651]. The IHS carries out this authority through contracts with and grants to UIOs. In March 2010, as part of the Affordable Care Act, Congress reauthorized and amended the IHCA. The reauthorization of the IHCA included a requirement that the IHS “confer,” to the maximum extent practicable, with UIOs in carrying out the IHCA.

**C. Policy.** It is IHS policy to confer with UIOs, to the maximum extent practicable, whenever a “critical event or issue,” as defined in this Notice, arises in implementing or carrying out the IHCA.