

**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.

**Animal Drug User Fee Cover Sheet; Form FDA 3546 (OMB Control Number 0910-0539)—Extension**

Under Section 740 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-12), as amended by Animal Drug User Fee Act (ADUFA) (Pub. L. 108-130), FDA has the authority to assess and collect for certain animal drug user fees. Because concurrent submission of user fees with

applications and supplements is required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The ADUFA cover sheet (Form FDA 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made is appropriately linked

to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

In the **Federal Register** of February 3, 2014 (79 FR 6199), 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>

FD&C Act section amended by ADUFA	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
740(a)(1) .....	3546 (Cover Sheet) ....	17	1 time for each application.	17	1	17

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

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's database system, there are an estimated 173 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the average number of submissions received by FDA in fiscal years 2011-2013. The estimated hours per response are based on past FDA experience with the various submissions. The hours per response are based on the average of these estimates.

Dated: April 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-09202 Filed 4-22-14; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-D-0090]

**Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of the draft guidance entitled "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval." This draft guidance clarifies FDA's current policy on balancing premarket and postmarket data collection during the Agency's review of premarket approval applications (PMA). Specifically, this guidance outlines how FDA considers the role of postmarket information in determining the appropriate type and amount of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of safety and effectiveness. FDA believes this guidance will improve patient access to safe and effective medical devices that are important to public health by improving the predictability, consistency, transparency, and efficiency of the premarket process. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 22, 2014.

**ADDRESSES:** An electronic copy of the guidance document is available for

download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002, 301-796-5900 or Stephen Ripley, Center for

Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA has long applied postmarket controls as a way to reduce premarket data collection, where appropriate, while assuring that the statutory standard for approval of reasonable assurance of safety and effectiveness is still met. The right balance of premarket and postmarket data collection facilitates timely patient access to important new technology without undermining patient safety.

In this draft guidance, FDA describes existing statutory requirements under the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and FDA policies that support the policy on balancing premarket and postmarket data collection during review of PMA applications. In addition, FDA clarifies how the Agency considers postmarket data as part of the benefit-risk framework described in FDA's guidance "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications," issued on March 28, 2012. This guidance provides a resource for industry and FDA staff on how FDA determines when it is appropriate for a sponsor of a PMA to collect some data (clinical or non-clinical) in the postmarket setting, rather than premarket.

Elsewhere in this issue of the **Federal Register**, FDA is announcing another draft guidance entitled "Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions," which also addresses the role of postmarket data and the benefit-risk framework as key elements of FDA's proposed "Expedited Access Program."

##### II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on balancing premarket and postmarket data collection for devices subject to premarket approval. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval," may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1833 to identify the guidance you are requesting.

##### IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 822 have been approved under OMB control number 0910-0449.

##### V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0363]

#### **Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of the draft guidance entitled "Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions." This draft guidance outlines FDA's proposal for a new, voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions and are subject to premarket approval applications (PMA). FDA believes that the Expedited Access PMA (EAP) program will help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standard of reasonable assurance of safety and effectiveness for premarket approval, consistent with the Agency's mission to protect and promote public health. The document also discusses how the EAP program approaches the balance of premarket and postmarket data collection and incorporates a benefit-risk framework. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 22, 2014.

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for