

- facilitate, identify, and prioritize technical assistance and development needs, develop strategic and project plans, and allocate resources to coordinate FDA training program components for U.S. teachers actively incorporating FDA's food safety and nutrition curriculum in their classrooms, as specified in the various training components of this proposed cooperative agreement.

### C. Eligibility Information

The following organization is eligible to apply: Graduate School USA.

## II. Award Information/Funds Available

### A. Award Amount

The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations, availability of funding and awardee performance.

FDA/CFSAN intends to fund up to \$452,700.00 for fiscal year 2015 in support of this grant program. Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

YR 1: \$452,700  
YR 2: \$500,000  
YR 3: \$500,000  
YR 4: \$500,000  
YR 5: \$500,000

### B. Length of Support

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

## III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at <http://www.grants.gov>. Search by Funding Opportunity Number: RFA-FD-15-011. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status

- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-13330 Filed 6-1-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-1805]

#### Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection; Correction

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

**ACTION:** Notice; request for comments; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled "Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection" that appeared in the **Federal Register** of April 29, 2015 (80 FR 23798). The document announced the progress of the Center for Devices and Radiological Health on its 2014-2015 Strategic Priority "Strike the Right Balance Between Premarket and Postmarket Data Collection." The document was published with the incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 29, 2015, in FR Doc. 2015-09884, on page 23798, the following correction is made:

1. On page 23798, in the first column, in the headings section of the document, "[Docket No. FDA-2014-D-0090]" is corrected to read "[Docket No. FDA-2015-N-1805]".

Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-13337 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-0248]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

**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 the information collection contained in the guidance for industry on formal dispute resolution.

**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](mailto: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.

#### **Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level (OMB Control Number 0910-0430)—Extension**

This information collection approval request is for FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the Agency will interpret and apply provisions of the existing regulations regarding internal Agency review of decisions (§ 10.75 (21 CFR 10.75)) and dispute resolution during the investigational new drug (IND) process (§ 312.48 (21 CFR 312.48)) and the new drug application/abbreviated new drug application (NDA/ANDA) process (§ 314.103 (21 CFR 314.103)). In addition, the guidance provides information on how the Agency will

interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the Agency, CDER, and CBER. All Agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in part 312 (OMB control number 0910-0014), part 314 (OMB control number 0910-0001), and part 601 (21 CFR part 601) (OMB control number 0910-0338), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(a)(11) and (d), 314.50, 314.94, and 601.2) state that information provided to the Agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571—OMB control number 0910-0014, and FDA Form 356h—OMB control number 0910-0338.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the Agency in triplicate with the appropriate form attached,

either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency’s tracking databases enables the appropriate Agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the Center may quickly and efficiently respond to the request: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (*i.e.*, scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last Agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the Agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA’s experience with dispute resolution, the Agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the Agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

*Description of Respondents:* A sponsor, applicant, or manufacturer of a drug or biological product regulated by

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 <sup>1</sup>

| 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           |
| <b>Total</b> .....                     |                       |                                    |                        |                             | <b>256</b>  |

<sup>1</sup> 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]

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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; 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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