

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

| 21 CFR section                   | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|----------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 895.21(d)(8) and 895.22(a) ..... | 26                    | 1                                  | 26                     | 16                          | 416         |
| Total .....                      | .....                 | .....                              | .....                  | .....                       | 441         |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

| 21 CFR section  | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|-----------------|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| 800.55(k) ..... | 1                       | 1                                  | 1                    | 20                               | 20          |

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

Dated: January 31, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-02529 Filed 2-5-13; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0536]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 8, 2013.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0511. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information

Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**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.

#### Medical Device User Fee Cover Sheet, Form FDA 3601—(OMB Control Number 0910-0511)—Extension

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107-250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the “Medical Device User Fee Cover Sheet,” is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA’s Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research to initiate the administrative screening of new medical

device applications and supplemental applications.

The total number of annual responses is based on the number of cover sheet submissions received by FDA in fiscal years 2009 through 2011. FDA received cover sheets for the following medical device submissions (average annual): 38 premarket approval applications (premarket approval application (PMA)), product development protocol (PDP), postmarketing requirement (PMR), biologics license application (BLA)), 3,561 premarket notifications, 12 panel track supplements, 180 real-time supplements, 127 180-day supplements, 749 30-day notices, 84 513(g) requests, and 463 annual fees for periodic reporting. The number of received annual responses included the cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes).

In the **Federal Register** of June 6, 2012 (77 FR 33469), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one PRA related comment.

The comment states that the cover sheet “can be obtained prior to payment of the fee and should not be available until payment of the fee has been confirmed.” It is unclear whether the comment addresses the topics on which the 60-day notice invited comment. As stated earlier in this document, the User Fee Cover Sheet is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to

account for and track user fees. MDUFMA requires the submission of the user fees concurrently with applications (21 U.S.C. 379j(a)(2)(C)). If

the required fees are not submitted, the review of the application will not begin. The User Fee Cover Sheet provides the

information necessary to either initiate or defer the application review.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

| Form FDA No. | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--------------|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 3601 .....   | 5,214              | 1                               | 5,214                  | 0.30                        | 1,564       |

Dated: February 1, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-02613 Filed 2-5-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2003-N-0453]

#### Training Program for Regulatory Project Managers; Information Available to Industry

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

**DATES:** Pharmaceutical companies may submit proposed agendas to the Agency by April 8, 2013.

**FOR FURTHER INFORMATION CONTACT:** Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4160, Silver Spring, MD 20993-0002, 301-796-0578, [dan.brum@fda.hhs.gov](mailto:dan.brum@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management

staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

##### II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

##### III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms interested in offering a site tour or learning more about this training opportunity should respond by submitting a proposed agenda to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: January 31, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-02523 Filed 2-5-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Advancing Translational Sciences (NCATS): Cooperative Research and Development Agreement (CRADA) and Licensing Opportunity for Small Molecule Agonists of the Relaxin Hormone Receptor (RXFP1) for Treatment of Heart Failure and Fibrosis

**SUMMARY:** The National Center for Advancing Translational Sciences (NCATS), the National Institutes of Health (NIH), is seeking Cooperative Research and Development Agreement (CRADA) partners to collaborate in the final stages of lead optimization, in vitro and in vivo evaluation, and preclinical development of a novel series of potent, selective, and orally bioavailable small molecule agonists of the relaxin hormone receptor, RXFP1, for the treatment of heart failure and fibrosis. Interested potential CRADA collaborators will receive detailed information on the current status of the project after signing a confidentiality