Dated: October 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26439 Filed 10–16–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0471]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 November 18, 2015.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0297. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

User Fee Cover Sheet; Form FDA 3397 (OMB Control Number 0910–0297)—Extension

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications (BLAs) and supplements to those applications. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications (NDAs), BLAs, or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, 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 of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs, BLAs, and/or, supplemental applications to those applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2014, there are an estimated 290 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105–115). The total number of annual responses is based on the number of submissions received by FDA in FY 2014. CDER received 3,005 annual responses that include the following submissions: 128 NDAs; 7 BLAs; 1,586 manufacturing supplements; 1,081 labeling supplements; and 203 efficacy supplements. CBER received 705 annual responses that include the following submissions: 11 BLAs; 611 manufacturing supplements; 64 labeling supplements; and 19 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions.

In the **Federal Register** of April 15, 2015 (80 FR 20232), 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 [1]

FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3397	290	12.79	3,710	0.5 (30 min.)	1,855

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

Dated: October 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0776]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reclassification Petitions for Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver