number. OMB has now approved the information collection and has assigned OMB control number 0910–0785. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13473 Filed 6–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0313]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings With the Office of Orphan Products Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings with the Office of Orphan Products Development'' 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 Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 4, 2015, the Agency submitted a proposed collection of information entitled, ''Guidance for Industry, Researchers, Patient Groups, and FDA Staff on Meetings with the Office of Orphan Products Development'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0787. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13472 Filed 6–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0882]

Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2012 Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to request that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA). The statutory authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the generic drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate by August 14, 2015.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *GenericDrugPolicy@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1718, Silver Spring, MD 20993–0002, 240–402–7946, *Connie.Wisner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect fees from drug companies that submit marketing applications for certain generic human drug applications, certain drug master files, and certain facilities. GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements. The statutory authority for GDUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human generic drug review process. Section 744C(d) (21 U.S.C. 379j–43(d)) of the FD&C Act requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts. FDA will initiate this process on June 15, 2015, by holding a public meeting at which stakeholders and other members of the public will be given an opportunity to present their views on reauthorization (80 FR 22204). The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, health care professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensuring progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this

notice will be included in all stakeholder discussions while FDA negotiates with the regulated industry. Stakeholders who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These stakeholder discussions will satisfy the requirement in section 744C(d)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding GDUFA reauthorization, please provide notification by email to *GenericDrugPolicy@fda.hhs.gov* by August 14, 2015. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13465 Filed 6–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0194]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Cover Sheet; Form FDA 3792

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 July 6, 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 0910–0718. 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.

Biosimilars User Fee Cover Sheet; Form FDA 3792

OMB Control Number 0910–0718—Extension

The Patient Protection and Affordable Care Act (Pub. L. 111–148) contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (Title VII Subtitle A) (BPCI Act) that amends the Public Health Service Act (42 U.S.C. 262) (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications in the definition of ''human drug application'' for the purposes of the prescription drug user fee provisions. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for fiscal years 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012.

FDA's biosimilar biological product user fee program requires FDA to assess and collect user fees for certain meetings concerning biosimilar biological product development (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fees submitted for a submission with the actual submission by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

In the **Federal Register** of January 27, 2015 (80 FR 4272), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Respondents to this collection of information are manufacturers of biosimilar biological product candidates. Based on the number of Form FDA 3792s we have received, we estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Biosimilars User Fee Cover Sheet; Form FDA 3792	20	1	20	0.50 (30 minutes)	10

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