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.

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13471 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–N–1459]

Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period in the notice of availability that appeared in the **Federal Register** of February 19, 2015. In that notice of availability, FDA requested comments on a draft standard memorandum of understanding (MOU) entitled ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration.'' The draft standard MOU describes the responsibilities of any State that chooses to sign the MOU in investigating and responding to complaints related to compounded human drug products distributed outside the State and in addressing the interstate distribution of inordinate amounts of compounded human drug products. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period in the notice of availability published on February 19, 2015 (80 FR 8874) which includes comment on information collection issues under the Paperwork Reduction Act of 1995 (the PRA). Submit either electronic or written comments on the draft standard MOU or on information collection issues under the PRA by July 20, 2015.

ADDRESSES: Submit written requests for single copies of the MOU to Edisa Gozun, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, suite 5100, Silver Spring, MD 20993–0002. Send one self-addressed label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft standard MOU.

Submit electronic comments on the new draft standard MOU or on the collection of information 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.

FOR FURTHER INFORMATION CONTACT: Edisa Gozun, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, suite 5100, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 19, 2015 (80 FR 8874), FDA published a notice of availability of a draft standard MOU entitled ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration'' with a 120-day comment period to request comments on the draft standard MOU. The draft standard MOU describes the responsibilities of any State that chooses to sign the MOU in: (1) Investigating and responding to complaints related to compounded human drug products distributed outside the State and (2) addressing the interstate distribution of inordinate amounts of compounded human drug products. Comments were also requested on information collection issues under the PRA. The notice of availability also announced the withdrawal, effective February 19, 2015, of an earlier draft standard MOU entitled ''Memorandum of Understanding on Interstate Distribution of Compounded Drug Products'' that published on January 21, 1999 (64 FR 3301). The January 1999 draft standard MOU is superseded by the February 2015 draft standard MOU.

The Agency is extending the comment period both for the draft standard MOU and for information collection issues under the PRA for 30 days, until July 20, 2015. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying resolution of these important issues.

II. Request for 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.*

III. Electronic Access

Persons with access to the Internet may obtain the draft standard MOU at *http://www.regulations.gov.*

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13466 Filed 6–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Graduate Psychology Education Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Class Deviation from Competition Requirements for Graduate Psychology Education Program from Open to Limited Competition.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing a limited competition for awards among the 40 current Graduate Psychology Education (GPE) Program grantees whose project periods end June 30, 2016. No more than $1,000,000 will be made available in federal fiscal year (FY) 2015 in the form of 1-year project period grants. These awards are specifically for interprofessional training of doctoral psychology graduate students and interns to address the psychological needs of military personnel, veterans, and their families in civilian and community-based settings, including those in rural areas. An estimated five grants will be awarded with a ceiling amount of $190,000 per grant for 1 year. These funds will be used to establish, expand, and/or enhance activities that were funded under the FY 2013 GPE Program.

Program funds are to be used for stipend support for interns and doctoral students, faculty development, curriculum and instructional design, program content enhancement, program infrastructure development, and the