DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Biosimilar User Fee Act; Stakeholder Meetings on Biosimilar User Fee Act of 2012 Reauthorization; Request for Notification of Regulated Industry Organization 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 industry trade associations, whose members include drug companies currently engaged in development or manufacture of biosimilar biological products in the U.S., or drug companies intending to engage in these activities during the period of FY 2018–2022, notify FDA of their intent to participate in industry stakeholder meetings in support of timely reauthorization of the Biosimilar User Fee Act of 2012 (BsUFA). The statutory authority for BsUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue collecting user fees to fund the biosimilar biological product review process. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA engage in negotiations with regulated industry to develop recommendations to present to Congress with respect to the reauthorization of BsUFA. The purpose of this request for notification is to ensure that qualifying industry organizations notify FDA of their intention to participate in the planned negotiation process.

DATES: Submit notification of intention to participate by October 30, 2015.

ADDRESSES: Submit notification of intention to participate in FDA-industry user fee negotiations by email to *biosimilars@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993, 301–796–1042, FAX: 301–847–3529; *sandra.benton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting that industry trade associations, whose members include drug companies currently engaged in development or manufacture of biosimilar biological products in the U.S., or drug companies intending to engage in these activities during the period of FY 2018–2022, notify the Agency of their intent to participate in FDA-industry negotiations on the reauthorization of BsUFA. BsUFA authorizes FDA to collect fees from the biosimilar biological product industry for certain activities relating to biosimilar biological product development, for certain types of applications and supplements for approval of biosimilar biological products, on establishments where approved biosimilar biological products are made, and on biosimilar biological products after approval. BsUFA fees finance critical and measurable aspects of FDA's biosimilar biological product review program. The statutory authority for BsUFA 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 biosimilar biological product review process. Section 744I(e) (21 U.S.C. 379j–53(e)) of the FD&C Act requires that FDA, in developing reauthorization recommendations to present to Congress, consult with a range of public and industry stakeholders including representatives from patient and consumer advocacy groups,health care professionals, scientific and academic experts, and the regulated industry. FDA will initiate this process on December 18, 2015, by holding a public meeting at which these key stakeholders and other members of the public will be given an opportunity to present their views on reauthorization. The FD&C Act further requires that after negotiations with the regulated industry are concluded, FDA shall present those recommendations for public review and comment, and finally transmit recommendations to Congress, revised as necessary based on public input, not later than January 15, 2017.

Consistent with FDA's approach to the Prescription Drug User Fee Act (PDUFA) industry stakeholder meetings, the BsUFA industry stakeholder meetings will include industry trade associations that represent biosimilar biological product manufacturers rather than individual companies. Accordingly, FDA is issuing this **Federal Register** notice to request that industry associations, whose members include drug companies currently engaged in the development or manufacture of biosimilar biological products in the U.S, or drug companies intending to engage in these activities during the period of FY 2018–2022, notify FDA of their intent to participate in the industry stakeholder meetings on BsUFA reauthorization.

Please notify FDA if you are a trade association interested in participating in this process by providing an email to *biosimilars@fda.hhs.gov* by October 30, 2015. Your email should contain complete contact information, including name, title, organization affiliation, address, email address, telephone number, and notice of any special accommodations required because of disability. It is anticipated that the negotiation process will begin within the first quarter of calendar year 2016 in order to ensure that FDA-industry negotiations can be concluded and the subsequent public consultation process conducted in advance of the statutory deadline in January 2017.

Dated: September 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24815 Filed 9–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–0281–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for revision of the approved information collection assigned OMB control number 0990–0281, scheduled to expire on November 30, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before October 30, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.