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.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0281 for reference.

Information Collection Request Title: Prevention Communication Formative Research—Revision—OMB No. 0990–0281—Office of Disease Prevention and Health Promotion.

Abstract: The Office of Disease Prevention and Health Promotion's (ODPHP) focus includes developing and disseminating prevention information to the public. Changes in this request include updated national hourly wage and minor changes to data collection activities and related burden hours in order to meet the needs of the initiatives mentioned below. This request builds on previous formative research approaches to place more emphasis on Web-based data collection to allow greater geographical diversity among respondents, to decrease respondent burden, and to save government costs. As a federal government agency, ODPHP strives to be responsive to the needs of America's diverse audiences while simultaneously serving all Americans across a range of channels. To carry out its prevention information efforts, ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of its disease prevention and health promotion communication and education efforts. This generic clearance request describes data collection activities involving methods such as: Individual interviews, focus groups, Web-based surveys, card sorting and various forms of usability testing to establish a deeper understanding of the interests and needs of consumers and health professionals for disease prevention and health promotion information and tools.

The information collected will be used by ODPHP to improve its communication, products, and services that support key office activities including: Healthy People, Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, healthfinder.gov, and increasing health care quality and patient safety. ODPHP communicates through its Web sites (*www.healthfinder.gov, www.HealthyPeople.gov, www.health.gov*) and through other channels including social media, print materials, interactive training modules, and reports.

Likely Respondents: Respondents are likely to be either consumers or health professionals.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Data collection task	Instrument/form name	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)	Total response burden (in hours)
In-depth interviews	Screener	135	1	10/60	22.5
	Interview	45	1	1	45
Focus groups	Screener	240	1	10/60	40
	Focus Group	80	1	1.5	120
Web-based surveys	Screener	6000	1	5/60	500
	Survey	2000	1	15/60	500
Card sorting	Screener	180	1	10/60	180
	Card Sort	60	1	1	60
Usability and prototype testing of materials (print and Web).	Screener	360	1	10/60	60
	Usability Test	120	1	1	120
Total					1,647.50

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–24702 Filed 9–29–15; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Clinical and Basic Science Review Committee.

Date: October 22–23, 2015.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Crystal City, 1800 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Keith A. Mintzer, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892–7924, 301–594–7947, *mintzerk@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 24, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–24690 Filed 9–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.