

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 75, Rm. 4736, Silver Spring, MD 20993, 240-402-7960, [Stephanie.Choi@fda.hhs.gov](mailto:Stephanie.Choi@fda.hhs.gov); or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 75, Rm. 4722, Silver Spring, MD 20993, 240-402-7957, [Robert.Lionberger@fda.hhs.gov](mailto:Robert.Lionberger@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

In July 2012, Congress passed GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and modernize the generic drug program. To support this goal, FDA agreed in the GDUFA commitment letter to work with industry and interested stakeholders on identifying regulatory science research priorities specific to generic drugs for each fiscal year covered by GDUFA. The commitment letter outlines FDA's performance goals and procedures under the GDUFA program for the years 2012-2017. The commitment letter can be found at <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>.

### II. Topics for Discussion at the Public Workshop

The purpose of the May public workshop is to obtain input from industry and other interested stakeholders on the identification of generic drug regulatory science priorities for FY 2018. FDA is holding this public workshop because the Agency intends to continue its regulatory science initiatives upon reauthorization of GDUFA (*i.e.*, GDUFA II) for FYs 2018-2022 (see Generic Drug User Fees; Public Meeting; Request for Comments, 81 FR 66035, September 26, 2016). To help fulfill its mission, FDA is particularly interested in receiving input on the following topics:

- Opportunities for scientific or technical advancements that would help to overcome specific barriers for industry that currently limit the availability of generic drug products.
- Innovative approaches to pre-approval development of generic drugs, including new methodologies for product design and manufacturing, and design and conduct of *in vitro*, *ex vivo*, and clinical studies and identification of scientifically robust strategies for demonstration of bioequivalence for various product classes.
- Innovation in scientific approaches to evaluating the therapeutic

equivalence of generic drug products throughout their life cycle.

- Identification of high-impact public health issues involving generic drugs that can be addressed by the prioritized allocation of FY 2018 funding for regulatory science research.
- Identification of specific issues related to generic drug products where scientific recommendations and/or clarifications are needed in developing and/or revising FDA's guidance for industry.
- Strategies for enhancing quality and equivalence risk management during generic drug product development, during regulatory review, and/or throughout the drug product's life cycle.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2018 regulatory science priorities. Additional information concerning GDUFA, including the text of the law and the commitment letter, can be found at <http://www.fda.gov/gdufa>.

### III. Participating in the Public Workshop

**Registration:** To register to attend "Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Workshop" in-person, or to attend virtually via web cast, please send an email to [GDUFARegulatoryScience@fda.hhs.gov](mailto:GDUFARegulatoryScience@fda.hhs.gov) by April 5, 2017. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Any person without email access can register by contacting Stephanie Choi (see **FOR FURTHER INFORMATION CONTACT**). If you need special accommodations because of a disability, please contact Stephanie Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 5, 2017, midnight eastern standard time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

**Requests for Oral Presentations:** During online registration you may indicate if you wish to present during the public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are

urged to consolidate or coordinate their presentations. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 19, 2017. All requests to make oral presentations must be received by the close of registration on April 5, 2017, midnight eastern standard time. If selected for presentation, any presentation materials must be emailed to [GDUFARegulatoryScience@fda.hhs.gov](mailto:GDUFARegulatoryScience@fda.hhs.gov) no later than April 26, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

**Streaming Webcast of the Public Workshop:** This public workshop will also be web cast. To join via the web cast, please go to <https://collaboration.fda.gov/gpw517/>. Please register in advance for web cast per the instructions provided in this section.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A link to the transcript will also be available on the Internet at <http://www.fda.gov/GDUFARegScience>.

Dated: March 9, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### National Advisory Council on the National Health Service Corps

**AGENCY:** Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, notice

is hereby given that a meeting is scheduled for National Advisory Council on the National Health Service Corps (NACNHSC). This meeting will be open to the public.

**DATES:** The meeting will be held on March 22, 2017 from 1:00 p.m.–4:00 p.m. EDT.

**ADDRESSES:** This meeting will be held in a webinar and conference call format. Webinar information can be found on the Web site at: <http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/meetingsummaries/index.html>.

**Agenda:** The members of the NACNHSC will discuss provider retention in rural areas, the redesign of Area Health Education Centers, as well as provide an update on Health Professional Shortage Area scoring. Agenda items are subject to change as priorities dictate. The NACNHSC final agenda will be available on the NACNHSC Web site 3 days in advance of the meeting.

Information about the NACNHSC and the agenda for this meeting can be obtained by accessing the following Web site: <http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/meetingsummaries/index.html>.

**FOR FURTHER INFORMATION CONTACT:**

Anyone requesting information regarding the NACNHSC should contact CAPT Shari Campbell, Designated Federal Official, Bureau of Health Workforce (BHW), HRSA in one of three ways: (1) Send a request to the following address: CAPT Shari Campbell, Designated Federal Official, BHW, HRSA, 5600 Fishers Lane, Room 14N108, Rockville, Maryland 20857; (2) call (301) 594-4251; or (3) send an email to [scampbell@hrsa.gov](mailto:scampbell@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The NACNHSC makes recommendations with respect to their responsibilities under Subpart II, Part D of Title III of the Public Health Service Act, as amended (National Health Service Corps and Health Professional Shortage Area Designations), and shall review and comment upon regulations promulgated by the Secretary under Subpart II.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the NACNHSC should be sent to Monica-Tia Bullock at [MBullock@hrsa.gov](mailto:MBullock@hrsa.gov) by March 17, 2017. Individuals who plan to attend and need special assistance, such as sign language

interpretation or other reasonable accommodations, should contact Monica-Tia Bullock at [MBullock@hrsa.gov](mailto:MBullock@hrsa.gov) by March 17.

**Jason E. Bennett,**

*Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: HHS-OS-0990-New]

#### 60-Day Notice Template for Request for Generic Clearance for the Collection of Routine Customer Feedback on HHS Communications

**AGENCY:** U.S. Department of Health and Human Services (HHS).

**ACTION:** Notice and request for comments. Office of the Assistant Secretary for Public Affairs is requesting OMB approval for a new Generic Clearance for the Collection of Routine Customer Feedback by OMB.

**SUMMARY:** Department of Health and Human Services, The Office of the Secretary (OS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” for approval under the Paperwork Reduction Act (PRA). This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

**DATES:** Consideration will be given to all comments received by May 15, 2017.

**ADDRESSES:** Submit comments by one of the following methods:

- *Web site:* [www.regulations.gov](http://www.regulations.gov).

Direct comments to Docket ID OMB-2010-0021.

- *Email:*

[Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov).

- *Phone:* (202) 690-6162.

Comments submitted in response to this notice may be made available to the public through relevant Web sites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email

comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

**FOR FURTHER INFORMATION CONTACT:**

Sherrette Funn, [Sherrette.funn@HHS.GOV](mailto:Sherrette.funn@HHS.GOV) or (202) 795-7714.

**SUPPLEMENTARY INFORMATION:**

*Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

*Abstract:* The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency’s services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per