

**STATUS:** Parts will be open to the public and part will be closed to the public.

**MATTERS TO BE CONSIDERED:**

**Open to the Public**

1. Approval of the Minutes of the May 23, 2016 Joint Board Member/ETAC Meeting
2. Monthly Reports
  - (a) Participant Activity Report
  - (b) Investment Performance Report
  - (c) Legislative Report
3. Vendor Financials

**Closed to the Public**

Information covered under 5 U.S.C. 552b(c)(9)(B).

**CONTACT PERSON FOR MORE INFORMATION:**

Kimberly Weaver, Director, Office of External Affairs, (202) 942-1640.

Dated: June 16, 2016.

**Megan Grumbine,**

*General Counsel, Federal Retirement Thrift Investment Board.*

[FR Doc. 2016-14591 Filed 6-16-16; 11:15 am]

**BILLING CODE 6760-01-P**

**GENERAL SERVICES  
ADMINISTRATION**

**[OMB Control No. 3090-0297; Docket No. 2016-0001; Sequence 3]**

**Submission for OMB Review; General Services Administration Acquisition Regulation; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery**

**AGENCY:** General Services Administration (GSA).

**ACTION:** Notice of request for an extension to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding the Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

**DATES:** Submit comments on or before July 20, 2016.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for “Information Collection 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.” Select the link “Submit a Comment” that corresponds with “Information Collection 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “Information Collection 3090-0297” on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. Attn: Ms. Flowers/IC 3090-0297, Generic Clearance.

**Instructions:** Please submit comments only and cite Information Collection 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

**FOR FURTHER INFORMATION CONTACT:** Ms. Hada Flowers, Office of Governmentwide Policy, GSA, at 202-501-4755, or email [hada.flowers@gsa.gov](mailto:hada.flowers@gsa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

A notice was published in the **Federal Register** at 81 FR 20638 on April 8, 2016. No comments were received. The information collection activity will 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.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance.

Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study.

Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results. The Digital Government Strategy released by the White House in May, 2012 drives agencies to have a more customer-centric focus. Because of this, GSA anticipates an increase in requests to use this generic clearance, as the plan states that: A customer-centric principle charges us to do several things: Conduct research to understand the customer's business, needs and desires; “make content more broadly available and accessible and present it through multiple channels in a program- and device-agnostic way; make content more accurate and understandable by maintaining plain language and content freshness standards; and offer easy paths for feedback to ensure we continually improve service delivery.

The customer-centric principle holds true whether our customers are internal (e.g., the civilian and military federal workforce in both classified and unclassified environments) or external (e.g., individual citizens, businesses, research organizations, and state, local, and tribal governments).”

**B. Annual Reporting Burden**

*Respondents:* 160,082.

*Responses per Respondent:* 1.

*Total Annual Responses:* 160,082.

*Hours per response:* 3.8386 minutes.

*Total Burden hours:* 10,241.

**C. Public Comments**

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

*Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 3090-0297, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, in all correspondence.

Dated: June 14, 2016.

**David A. Shive,**

*Chief Information Officer.*

[FR Doc. 2016-14509 Filed 6-17-16; 8:45 am]

BILLING CODE 6820-34-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2016-D-0734]

**Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies." The purpose of this document is to outline FDA's proposed recommendations and expectations for the evaluation and reporting of age, race, and ethnicity data in medical device clinical studies. The primary intent of these recommendations is to improve the quality, consistency, and transparency of data regarding the performance of medical devices within

specific age, race, and ethnic groups. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 19, 2016.

**ADDRESSES:** You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

**Written/Paper Submissions**

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2016-D-0734 for "Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical

Studies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and