
Instructions: Comments may be posted on OGE’s website, www.oge.gov. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Grant Anderson at the U.S. Office of Government Ethics; telephone: 202–482–9318; TTY: 800–877–8339; Email: ganderso@oge.gov.

SUPPLEMENTARY INFORMATION:

Title: Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

Abstract: The proposed information collection provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the agency’s commitment to improving service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions, but is not a statistical survey that yields 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. OGE expects to use various methods (e.g., focus groups, customer satisfaction surveys, comment cards) to solicit feedback. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public and other agency stakeholders. 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 non-controversial;
- The collections are focused on the awareness, understanding, attitudes, preferences, or experiences of the public or other stakeholders in order to improve existing or future services, products, or communication materials;
- Personally identifiable information (PII) is collected only to the extent necessary;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release to the public;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does 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 to 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.

As a general matter, information collections submitted under this generic clearance will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

OMB Number: 3209–0010.

Type of Request: Extension.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0431]

Food and Drug Administration Public Meeting on Financial Efficiency of Human Drug User Fee Programs; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled “FDA Public Meeting on Financial Efficiency of Human Drug User Fee Programs.” The topic to be discussed is the financial transparency and efficiency of the Prescription Drug User Fee Act, the Biosimilar User Fee Act, and Generic Drug User Fee Amendments.

DATES: The public meeting will be held on June 18, 2021, from 9:30 a.m. to 11:30 a.m. Eastern Time via WebEx Events. Submit either electronic or written comments on this public meeting by July 19, 2021. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held virtually due to extenuating circumstances.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 19, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 19, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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 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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comments, 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–2021–N–0431 for “FDA Public Meeting on Financial Efficiency of Human Drug User Fee Programs.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Monica Ellerbe, Food and Drug Administration, Office of Finance, Budget, Acquisition, and Planning, 4041 Powder Mill Rd., Rm. 72044, Beltsville,