



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0487]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0697. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

OMB Control Number 0910-0697--Extension

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 following: 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.

Respondents to this collection of information cover a broad range of stakeholders who have specific characteristics related to certain products or services regulated by FDA. These stakeholders include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction.

In the *Federal Register* of April 3, 2020 (85 FR 18989), we published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Focus groups	800	1	800	1.75	1,400
Customer comment cards/forms	1,325	1	1,325	.25 (15 minutes)	331.25
Small discussion groups	800	1	800	1.75	1,400
Customer satisfaction surveys	12,000	1	12,000	.33 (20 minutes)	3,960
Usability Studies	800	1	800	1.75	1,400
Total					8,491.25

In the 60-day notice published on April 3, 2020, the number of responses and number of burden hours did not match OMB approved inventory. This notice corrects the burden in table 1 of that notice. In addition, the burden for this collection of information has increased by 800 responses from 14,925 to 15,725 responses due to an inadvertent omission of responses of usability studies for this collection. This addition to responses will correct the number of responses for this collection. The burden hours in OMB's inventory will remain the same.

Dated: October 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-24422 Filed: 11/3/2020 8:45 am; Publication Date: 11/4/2020]