



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 Food and Drug Administration 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 (PRA).

DATES: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0697. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRStaff@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 FDA 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, FDA means information that provides useful insight on perceptions and opinions, not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insight 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. This information collection will allow for ongoing collaborative and actionable communications among the FDA 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 the 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, the

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.

In the Federal Register of April 29, 2014 (79 FR 23980), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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	725	1	725	1.75	1,269
Customer comment cards/forms	1,200	1	1,200	0.25 (15 minutes)	300
Small discussion groups	725	1	725	1.75	1,269
Customer satisfaction surveys	6,450	1	6,450	0.33 (20 minutes)	2,129
Total					4,967

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.