

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) ²	Total hours
Pretest	5	1	5	20/60	1.65
Survey	100	1	100	20/60	33
Total					34.65

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

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60”.

FDA calculated the total annual responses by multiplying the number of respondents by the annual frequency. FDA calculated the total hours by multiplying the estimated hours per response (20 minutes = 0.33 hours) by the number of respondents.

Dated: May 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0327]

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: Fax written comments on the collection of information by June 22, 2011.

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 e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–New and title “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.” Also include

the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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—NEW)

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 respondent) and are low cost for both the respondents and the Federal Government;
 - The collections are noncontroversial and do not raise issues of concern to other Federal Agencies;
 - Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
 - Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
 - Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the Agency (if released, the Agency must indicate the qualitative nature of the information);
 - 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 nonresponse 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 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.

Current Actions: New collection of information.

Type of Review: New collection.

Affected Public: Individuals and households, businesses and organizations, State, local, or Tribal Government.

Estimated Number of Respondents: Following is a preliminary estimate of the aggregate burden hours for this generic clearance. This estimate based

on a review of past behavior of the participating Agencies and by several individual Agencies' estimates for this information collection request. In recognition that individual Agencies will differ in how often they use this generic clearance, this burden estimate assumes that 10 Agencies would be the heaviest users and account for approximately 10 times as great a burden as the other Agencies combined. Agencies will provide more refined individual estimates of burden in their subsequent notices.

Average Expected Annual Number of Activities: 25,000.

Average Number of Respondents per Activity: 200.

Annual Responses: 5,000,000.

Frequency of Response: Once per request.

Average Minutes per Response: 30.

Burden Hours: 2,500,000.

Request for Comments: Comments submitted in response to this document will be summarized and/or included in the request for OMB approval. Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques or other forms of information technology; and (5) estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal Agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

In the **Federal Register** of December 22, 2010 (75 FR 80542), OMB published a 60-day notice requesting public comment on the proposed collection of information. All written comments will be available for public inspection at <http://www.regulations.gov>.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

44 U.S.C. 3501	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total expected annual number of activities	Average minutes per response
	200	1	5,000,000	2,500,000	25,000	30

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

Dated: May 12, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0322]

Agency Information Collection Activities; Proposed Collection; Comment Request; Manufacturer's Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the eligibility criteria and the process to be followed by establishments when notifying FDA of a manufacturer's intent