

Customer/Partner Service Surveys

OMB Control Number 0910-0360—
Extension

Under section 1003 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the Agency. Executive Order 12862, entitled “Setting Customer Service Standard,” directs Federal Agencies that “provide significant services directly to the public” to “survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.” FDA is seeking extension of an existing OMB clearance to conduct a series of surveys to implement Executive Order 12862.

Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as food processors; cosmetic, drug, biologic, and medical device manufacturers; consumers; and health professionals. The request also covers “partner” (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, courtesy, and problem resolution in the context of individual programs.

FDA estimates conducting 15 customer/partner service surveys per

year, each requiring an average of 15 minutes for review and completion. We estimate respondents to these surveys to be between 100 and 20,000 customers. Some of these surveys will be repeats of earlier surveys for purposes of monitoring customer/partner service and developing long-term data.

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.

In the **Federal Register** of January 21, 2020 (85 FR 3389), we 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 BURDEN ¹

Type of survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Mail, telephone, web-based	55,000	1	55,000	0.25 (15 minutes)	13,750

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-18244 Filed 8-19-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1206]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of July 7, 2020. The document

announced the dates that support and requirement will begin for version 1.7 of the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model (SDTM) Implementation Guide (IG) 3.3, and for version 2.1 of the Define-Extensible Markup Language (Define-XML). The document provided the incorrect dates for these electronic study data standards. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT:

Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 301-796-0035, cderdatastandards@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 7, 2020 (85 FR 40658), in FR Doc. 2020-14512, the following correction is made:

On page 40659, in the first column, the last three sentences of the document are corrected to read as follows:

“Support for version 1.7 of the CDISC SDTM IG 3.3 and version 2.1 of the Define-XML will begin on March 15, 2021, and the date that the requirement

begins for CDISC version 1.7 SDTM IG 3.3 and version 2.1 of the Define-XML for new drug applications, abbreviated new drug applications, certain biologics license applications, and noncommercial investigational new drug applications will be March 15, 2022. Support and requirement for version 1.3 of the CDISC SDTM IG 3.1.3 will end on March 15, 2021.”

Dated: August 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-18236 Filed 8-19-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-6098]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration-Regulated Products)

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 September 21, 2020.

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 0910–0497. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10:00 a.m.–12:00 p.m., 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.

Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)

OMB Control Number 0910–0497—Extension

FDA conducts focus group interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of consumers’ attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- to better understand consumers’ attitudes and emotions in response to topics and concepts, and
- to further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine their ideas but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

Respondents to this collection of information will include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA’s jurisdiction. Inclusion and exclusion criteria will vary depending on the research topic.

In the **Federal Register** of January 8, 2020 (85 FR 916), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments. FDA thanks the commenters for their comments and provides our response below. The first and second comments strongly support the proposed information collection related to focus groups used by the FDA. The third comment was 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 BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus Group Interviews	8,800	1	8,800	1.75	15,400

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–18243 Filed 8–19–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4620]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Reports of Corrections and Removals

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 September 21, 2020.

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 0910–0359. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD