

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity/section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—mandatory reports.	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—voluntary reports.	4	1	4	0.25 (15 minutes)	1
Total	301

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

Recordkeeping: As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications under section 417 of the FD&C Act for a period of 2 years. Based on past FDA experiences, we estimate that each mandatory report and its associated notifications will require 30 minutes of recordkeeping for the 2-year period, or 15 minutes per record per year. The annual recordkeeping burden for mandatory reportable food reports and their associated notifications is thus estimated to be 300 hours (1,200 × 0.25 hours).

We do not expect that records will always be kept in relation to voluntary reportable food reports. Therefore, we estimate that records will be kept for four voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 1 hour annually (4 × 0.25 hours). The estimated total annual recordkeeping burden will be 301 hours annually (1,200 × 0.25 hours) + (4 × 0.25 hours). This annual burden is shown in table 2.

Dated: September 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–20283 Filed 9–21–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Customer/Partner Service Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 October 23, 2017.

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0360. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Customer/Partner Service Surveys

OMB Control Number 0910–0360—Extension

Under section 903 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 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, and 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.

In the **Federal Register** of June 7, 2017 (82 FR 26497), 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

Type of survey	Number of respondents	Annual frequency per response	Hours per response	Total hours
Mail, telephone, web-based	55,000	1	.25 (15 minutes)	13,750

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

Dated: September 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20246 Filed 9–21–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5525]

Statistical Approaches To Evaluate Analytical Similarity; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Statistical Approaches to Evaluate Analytical Similarity.” This draft guidance, when finalized, will provide advice on the evaluation of analytical similarity to sponsors interested in developing biosimilar products. Specifically, this draft guidance describes the type of information a sponsor of a proposed biosimilar product should obtain about the structural/physicochemical and functional attributes of the reference product, how that information is used in the development of an analytical similarity assessment plan for the proposed biosimilar, and the statistical approaches recommended for evaluating analytical similarity.

DATES: Submit either electronic or written comments on the draft guidance by November 21, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 and 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 comment, 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–2017–D–5525 for “Statistical Approaches to Evaluate Analytical Similarity; Draft Guidance for Industry; Availability.” Received comments 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.

- *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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillendale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**