

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Awardee activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records related to Initial Report	400	1	400	0.5 hour (30 minutes)	200
Records related to Progress Reports	400	2	800	0.5 hour (30 minutes)	400
Records related to Supplement or Followup Report (if applicable).	100	1	100	0.5 hour (30 minutes)	50
Total					650

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

Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the project and compiling reports. Respondents should use current record

retention capabilities for electronic or paper storage to achieve these activities. We assume it will take 0.5 hour/year to ensure the documents related to submitting a request to participate in the

program are retained properly according to their existing recordkeeping policies, but no less than 3 years, as recommended by FDA (table 2).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Awardee activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Coordination with partnering entities related to Initial Report	300	2	600	8	4,800
Coordination with partnering entities related to Progress Reports	300	4	1,200	8	9,600
Coordination with partnering entities related to Supplement or Followup Report (if applicable)	100	2	200	8	1,600
Total					16,000

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

For those pilot projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. We estimate that 300 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. We assume each respondent will spend 8 hours coordinating with each partnering entity on each response for this pilot. We estimate that seven respondents will need to coordinate with an average of two partnering entities to create progress reports and the final report to submit to FDA (table 3).

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1216]

Electronic Study Data Submission; Data Standards; Technical Rejection Criteria for Study Data Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration’s (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing the effective date for Electronic Common Technical Document (eCTD) validations referenced in FDA’s “Technical Rejection Criteria for Study Data” (TRC).

DATES: The eCTD validations will become applicable on September 15, 2021.

ADDRESSES: You may submit either electronic or written comments 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-2018-D-1216 for “Electronic Study Data Submission; Data Standards; Technical Rejection Criteria for Study Data Effective Date.” 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, 240-402-7500.

- *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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Jonathan Resnick, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993-0002, 301-796-7997, Jonathan.Resnick@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, Stephen.Ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In accordance with the guidance¹ for industry “Providing Regulatory Submissions in Electronic Format—Standardized Study Data,” submissions that are not submitted electronically and electronic submissions that are not in a format that FDA can process, review, and archive will not be filed or received, unless they have an exemption or waiver from the electronic submission requirements. The Agency can process, review, and archive electronic submissions of study data that use the standards specified in the Data Standards Catalog posted to FDA’s Study Data Standards Resources web page (<https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>).

The technical rejection criteria are automated validations by the CDER or CBER inbound processing system using the specifications set forth in FDA’s “Specifications for eCTD Validation Criteria” to determine compliance with the requirement to submit electronic standardized study data. The eCTD validations referenced in FDA’s TRC will become effective on September 15, 2021. Starting September 15, 2021, FDA will reject submissions that contain any high validation errors included in the TRC. The latest version of the TRC is available on FDA’s web page on Study Data for Submission to CDER and CBER (<https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber>).

¹ Under section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(a)), at least 24 months after the issuance of a final guidance document in which FDA has specified the electronic format for submitting certain submission types to the Agency, such content must be submitted electronically and in the format specified by FDA.

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0547]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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: Submit written comments (including recommendations) on the collection of information by August 30, 2021.

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 0910-0744. 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, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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.