

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
<b>PHASE 2 ESTIMATES</b>					
First follow-up survey—participants .....	8,000	2,667	1	0.83	2,214
Second follow-up survey—participants .....	8,000	2,667	1	0.83	2,214
Service receipt tracking—program staff .....	200	67	250	0.08	1,340
Staff characteristics survey—program staff .....	200	67	1	0.42	28
Program leadership survey—program leaders .....	50	17	1	0.25	4
Semi-structured program discussion guide—program lead-ers .....	40	13	1	1.5	20
Semi-structured program discussion guide—program su-pervisors and partners .....	80	27	1	1.0	27
Semi-structured program discussion guide—program staff, providers .....	80	27	1	0.75	20
Semi-structured employer discussion guide—employers ....	50	17	1	1.0	17
In-depth participant interview guide—participants .....	200	67	1	2.0	134
Cost workbook—program staff .....	40	13	1	32.0	416
Estimated Total Annual Burden Hours, Phase 2: .....					6,434

**Authority:** Section 413 of the Social Security Act, as amended by the FY 2017 Consolidated Appropriations Act, 2017 (Public Law 115–31).

**Mary B. Jones,**  
ACF/OPRE Certifying Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA–2019–N–3077; FDA–2013–N–0403; FDA–2013–N–0579; FDA–2016–N–2474; FDA–2013–N–0717; FDA–2018–N–3728; FDA–2013–N–0797; FDA–2013–N–0578; FDA–2013–N–0879; FDA–2012–N–0197; FDA–2016–N–3586; FDA–2016–N–4319; and FDA–2013–N–0764]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**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](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <http://www.reginfo.gov/public/do/PRAMain>. 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities .....	0910–0883	1/31/2021
Protection of Human Subjects; Informed Consent; and Institutional Boards .....	0910–0130	1/31/2023
Biological Products: Reporting and Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Deviations in Manufacturing .....	0910–0458	1/31/2023
Reporting Associated with Designated New Animal Drugs for Minor Use and Minor Species .....	0910–0605	1/31/2023
Evaluation of the Food and Drug Administration’s General Market Youth Tobacco Prevention Campaign .....	0910–0753	1/31/2023
Collection of Conflict of Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs .....	0910–0882	1/31/2023
Human Tissue Intended for Transplantation .....	0910–0302	2/28/2023
General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h .....	0910–0338	2/28/2023
Procedures for the Safe Processing and Importing of Fish and Fishery Products .....	0910–0354	2/28/2023
Medical Devices; Shortages Data Collection System .....	0910–0491	2/28/2023
Focus Groups About Drug Products as Used by the Food and Drug Administration .....	0910–0677	2/28/2023

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB Control No.	Date approval expires
Unique Device Identification System .....	0910–0720	2/28/2023
Animal Feed Regulatory Program Standards .....	0910–0760	2/28/2023

Dated: March 11, 2020.

**Lowell J. Schiller,**  
Principal Associate Commissioner for Policy.  
[FR Doc. 2020–05354 Filed 3–16–20; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
[Docket No. FDA–2020–N–0908]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 information collection provisions of FDA’s regulations for submission of petitions, including food and color additive petitions (FAPs and CAPs) (including labeling) submission of information to a master file in support of petitions, and electronic submission using Form FDA 3503.

**DATES:** Submit either electronic or written comments on the collection of information by May 18, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 18, 2020. The <https://www.regulations.gov>

electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 18, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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–

2020–N–0908 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions; and Electronic Submission Using Food and Drug Administration Form 3503.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.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