

use of differential response, from the state during the year.

(5) The number of deaths in the state during the year resulting from child abuse or neglect.

(6) Of the number of children described in paragraph (5), the number of such children who were in foster care.

(7)

(a) The number of child protective service personnel responsible for the — (i.) intake of reports filed in the previous year;

(ii.) screening of such reports;

(iii.) assessment of such reports; and

(iv.) investigation of such reports.

(b) The average caseload for the workers described in subparagraph (A).

(8) The agency response time with respect to each such report with respect to initial investigation of reports of child abuse or neglect.

(9) The response time with respect to the provision of services to families and children where an allegation of child abuse or neglect has been made.

(10) N/A for NCANDS.

(11) The number of children reunited with their families or receiving family preservation services that, within five years, result in subsequent substantiated reports of child abuse or neglect, including the death of the child.

(12) The number of children for whom individuals were appointed by the court to represent the best interests of such children and the average number of out of court contacts between such individuals and children.

(13) N/A for NCANDS.

(14) N/A for NCANDS.

(15) The number of children referred to a child protective services system under subsection (b)(2)(B)(ii).

(16) The number of children determined to be eligible for referral, and the number of children referred, under subsection (b)(2)(B)(xxi), to agencies providing early intervention services under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*).

(17) The number of children determined to be victims described in subsection (b)(2)(B)(xxiv).

(18) The number of infants — (a) identified under subsection (b)(2)(B)(ii);

(b) for whom a plan of safe care was developed under subsection (b)(2)(B)(iii); and

(c) for whom a referral was made for appropriate services, including services for the affected family or caregiver, under subsection (b)(2)(B)(iii).

The items listed under number (10), (13), and (14) are not collected by NCANDS.

The Children’s Bureau proposes to continue collecting the NCANDS data through the two files of the Detailed Case Data Component, the Child File (the case-level component of NCANDS) and the Agency File (additional aggregate data, which cannot be collected at the case level). There are no proposed changes to the NCANDS data collection instruments. Small changes were made to streamline the instructions to provide clarity.

Respondents: State governments, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Information collection title	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Detailed Case Data Component: (Child File and Agency File) IT Staff	52	1	42.6	2,215.2
Detailed Case Data Component: (Child File and Agency File) Programmatic Staff	52	1	65.4	3,400.8
Estimated Annual Burden Total	5,616

Authority: 42 U.S.C. 5101 *et seq.*

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0809]

Recommendations on Scale-Up and Postapproval Changes Guidances for Industry; Request for Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is

reopening the comment period for the request for information and comments that appeared in the **Federal Register** of March 3, 2026. In the notice, FDA requested comments on the Agency’s series of guidances for industry on scale-up and postapproval changes for specific dosage forms. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the request for information and comments published on March 3, 2026 (91 FR 10397). Either electronic or written comments must be submitted by July 13, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 13, 2026. Comments received by mail/hand delivery/courier (for written/

paper submissions) will be considered timely if they are received 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-2026-N-0809 for “Recommendations on Scale-Up and Postapproval Changes Guidances for Industry; Request for Comments.” 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, 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:

Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993-0002, 301-796-6341, cder-quality-policy@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 3, 2026, FDA (91 FR 10397), published a request for information and comments with a 90-day comment period to request information and comments on the Agency’s series of guidances for industry on scale-up and postapproval changes for specific dosage forms. FDA received requests to extend the comment period to allow sufficient time to develop and submit meaningful comments. FDA has considered the requests and is reopening the comment period for an additional 30 days, until July 13, 2026. The Agency believes that this extension allows adequate time for interested persons to submit comments.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0498]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Procedures for the Safe Processing and Importing of Fish and Fishery 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 July 13, 2026.

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 0910-0354. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8758, 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.

Procedures for the Safe Processing and Importing of Fish and Fishery—21 CFR Part 123

OMB Control Number 0910-0354—Reinstatement

This information collection supports regulations in part 123 (21 CFR part 123), which mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA’s statutory authority to regulate food safety, including section 402(a)(1) and (4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (4)). Certain provisions in part 123 require that processors and importers of seafood collect and record information.

The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor’s HACCP plan (e.g., the