requirement for evaluation of practices and programs to improve activities such as identification, screening, medical diagnosis, forensic diagnosis, health evaluations, and services, including activities that promote collaboration between (1) the child protective service system; and (2) (i) the medical community, including providers of mental health and developmental disability services; and (ii) providers of early childhood intervention services and special education for children who have been victims of child abuse or neglect.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2023–22676 Filed 10–12–23; 8:45 am]

**BILLING CODE 4184–29–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Tribal Child Support Enforcement Direct Funding Request: (Office of Management and Budget #0970–0218)

**AGENCY:** Office of Child Support Services, Administration for Children and Families, United States Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Office of Child Support Services (OCSS), Administration for Children and Families (ACF) is requesting proposed revisions to an approved information collection the Tribal Child Support Enforcement Direct Funding Requests—(Office of Management and Budget (OMB) #0970–0218, expiration March 31, 2026). We are proposing a new requirement for tribes or tribal organizations to provide that charging fees and recovering costs will not be permitted.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The final rule within 45 CFR part 309, published in the **Federal Register** on March 30, 2004, contains a regulatory reporting requirement that, in order to receive funding for a tribal IV–D program, a tribe or tribal organization must submit a plan describing how the tribe or tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity; establishing, modifying, and enforcing support orders; and locating noncustodial parents. The plan is required for all tribes requesting funding; however, once a tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a tribe makes changes to its title IV–D program. If a tribe or tribal organization intends to make any substantial or material changes, a tribal IV–D plan amendment must be submitted for approval. Tribes and tribal organizations must have an approved plan and submit any required plan amendments to receive funding to operate a tribal IV–D program.

With this request to revise an approved information collection, OCSS proposes a new requirement for tribes and tribal organizations to provide that charging fees and recovering costs will not be permitted. This is due to the Elimination of the Non-Federal Share notice of proposed rulemaking published on April 21, 2023 (see 88 FR 24526). Tribes and tribal organizations that charge fees and recover costs must submit a plan amendment demonstrating compliance with the proposed new requirement, in accordance with 45 CFR 309.35(d). This notice invites comments on this proposed change and the related burden implications. This would be a onetime submission that would be implemented in conjunction with the issuing of a Final Rule. Only three tribal child support programs report data on the collection of fees and recovered costs.

*Respondents:* Tribes and tribal Organizations.

**Burden Estimates**

The following burden estimates are specific to burden associated with the proposed change in requirement. For information about currently approved burden under OMB #: 0970–0218, which is not expected to change, see information here: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202212-0970-012.*

| Instrument | Total number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| 45 CFR part 309—Plan Amendment—Charging fees and recovering costs .. | 3 | 1 | 3 | 9 |

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* Title IV–D of the Social Security Act; 45 CFR part 309.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2023–22630 Filed 10–12–23; 8:45 am]

**BILLING CODE 4184–41–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–1189]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importation of Prescription Drugs

**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:** Submit written comments (including recommendations) on the collection of information by November 13, 2023.

**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 0910–0888. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

**Importation of Prescription Drugs**

*OMB Control Number 0910–0888—Extension*

This information collection supports implementation of section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384), and applicable regulations in part 251 (21 CFR part 251), which provide for the importation of certain prescription drugs shipped from Canada. The purpose of section 804 of the FD&C Act is to reduce the cost of covered products to American consumers without imposing additional risk to public health and safety. The regulations in part 251 set forth procedures Section 804 Importation Program sponsors (SIP Sponsors) must follow when submitting plans to implement time-limited programs to begin importation of drugs from Canada. The regulations also establish criteria for FDA review and authorization of a SIP proposal or supplemental proposal. Additionally, the regulations set forth requirements for eligible prescription drugs and requirements for entities that engage in importation of eligible prescription drugs. Finally, the regulations provide that eligible prescription drugs that meet certain requirements are exempt from section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)).

*Description of Respondents:* Respondents to the collection of information are SIP Sponsors (States or Indian Tribes, or in certain future circumstances, pharmacists or wholesale distributors, and any cosponsor(s)), importers (pharmacists or wholesaler distributors), and manufacturers of eligible prescription drugs.

In the **Federal Register** of June 8, 2023 (88 FR 37549), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment communicating that we had revised our burden estimates from those found in the final rule that issued October 1, 2020 (85 FR 62094). The comment also suggested that our figures underestimated burden associated with individual provisions established by part 251 although no alternative figures were proffered. We note also, that both FDA and respondents continue to carry out certain provisions in part 251, including activities related to the information collection elements. The comment also appeared to question how FDA derived its count of respondents included in the information collection. In this regard, we note that the scope of the information collection is set forth in § 251.1. We appreciate all comments but refrain from making further modifications to our estimate until we have more experience with the implementation of the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR section 251; information collection activity | Number of respondents | Number of records per recordkeeper | Total annual records | Average burden per record (hours) | Total hours |
|---|---|---|---|---|---|
| Subpart B; SIP proposals and pre-import requests | 40 | 1.5 | 60 | 72 | 4,320 |
| Subpart C; Certain requirements for importation programs | 40 | 1 | 40 | 43 | 1,720 |
| Total | | | 100 | | 6,040 |

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

We assume burden attributable to the information collection tasks will be averaged and distributed among respondents. As noted in the previous submission, FDA estimates that there will be 10 SIP Sponsors requiring 360 hours each to research, prepare, and administer requirements annually; 10 Pre-Import Requests requiring 24 hours each annually; and 20 manufacturers also requiring 24 hours each annually to participate in the program. In addition, FDA estimates that a recordkeeping burden of 52 hours will be imposed annually on the 10 SIP Sponsors, and a recordkeeping burden of 24 hours will be imposed annually on each of the 10 Importers and the 20 manufacturers. The 20 manufacturers anticipated to participate in the program will also incur an estimated burden of 24 hours each for copying and providing records to SIP Sponsors and Importers of foreign transactions.

We have established a web page at *https://www.fda.gov/about-fda/reports/importation-program-under-section-804-fdc-act* to communicate news and information about FDA efforts to implement the Section 804 Importation Program. To date, no SIP proposals have been authorized since publication of the final rule on October 1, 2020. We have therefore retained figures from the previous information collection approval. We assume burden attributable to the required retention, reporting and disclosure of records pertaining to these information collection activities will be distributed among respondents for an average of 100 responses and 6,040 hours annually.

Dated: October 10, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–22653 Filed 10–12–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–4066]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Recall Regulations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) 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 FDA Recall Regulations.

**DATES:** Either electronic or written comments on the collection of information must be submitted by December 12, 2023.

**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 December 12, 2023. 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–2023–N–4066 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Recall Regulations.'' 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:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the