Authority: 22 U.S.C. 7105.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28819 Filed 12–6–24; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Child Support Portal Registration (Office of Management and Budget #: 0970–0370)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. 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 the federal Office of Management and Budget (OMB) approve the ''Child Support Portal Registration,'' with minor revisions, for an additional three years. The OCSS Child Support Portal (''Portal'') contains applications to help state child support agencies administer their programs. Authorized Portal users must register with OCSS to access Portal applications and provide OCSS with certain Portal application preferences. The current OMB approval expires on February 28, 2025.

DATES: Comments due January 8, 2025. OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OCSS maintains the Portal, which contains various applications through which authorized users may view, update, upload, or download information for child support purposes. Authorized users must register to access the Portal. The OCSS Portal authenticates registrants and then creates secure profiles for authorized users for employers, insurers, and financial institutions based on information provided in the Employer Services Profile and Insurance Match Debt Inquiry Portal Agreement and Profile forms. Information provided in the electronic National Medical Support Notice (e-NMSN), the electronic Incoming Withholding Order (e-IWO), and the Federally Assisted State Transmitted (FAST) Levy Financial Institution Profile forms gives OCSS the necessary information to set up the respective program user's process and capture preferences. State child support agencies manage and authenticate authorization for individual users via the state proxy server; therefore, a Portal Registration form is not required. State users must, however, provide OCSS with their respective Portal preferences. The information OCSS collects for the Portal registration and profiles remains the same but they underwent minor clarification revisions and edits to update ''Office of Child Support Enforcement (OCSE)'' to ''Office of Child Support Services (OCSS).'' OCSS revised the ''Registration Screen'' burden after the 60-day notice published to correctly reflect the current number of respondents and removed ''agreement'' from the Employer Services Profile form. OCSS also removed the e-NMSN Plan Administrator form because there are no respondents.

Respondents: Employers, Financial Institutions, Insurers, and State Child Support Agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total annual estimated number of respondents	Total annual number of responses per respondent	Average burden hours per response	Total annual burden hours
Portal Registration Screens	16,268	1	0.15	2,440.20
Employer Services Profile	20,040	1	0.08	1,603.20
e-NMSN: Employer Profile	20	1	0.22	4.40
e-NMSN: State Profile	4	1	0.22	0.88
e-IWO Employer/Payroll Provider Profile	117	1	0.08	9.36
Insurance Match Debt Inquiry Agreement and Profile	6	1	0.08	0.48
FAST Levy Financial Institution Profile	2	1	0.08	0.16

Estimated Total Annual Burden Hours: 4,058.68.

Authority: 42 U.S.C. 653(m)(2) and 44 U.S.C. 3554.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28761 Filed 12–6–24; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0481]

Standardized Format for Electronic Submission of Marketing Application Content for the Planning of Bioresearch Monitoring Inspections for Center for Drug Evaluation and Research Submissions; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of the guidance for industry entitled ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions.'' This guidance describes the electronic submission of certain data and information in standardized formats. This information is used by the Center for Drug Evaluation and Research (CDER) in the planning of, and by FDA's Office of Inspections and Investigations (OII) in the conduct of, BIMO inspections.

DATES: The announcement of the guidance is published in the **Federal Register** on December 9, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–0481 for ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 ''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.

You may submit comments on any guidance at any time ((see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0980.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring Inspections (BIMO) for CDER Submissions.'' This guidance describes the electronic submission of certain data and information in standardized formats. CDER uses the data and information described in the guidance to plan BIMO inspections. The guidance addresses major (*i.e.,* pivotal) studies used to support safety and efficacy claims in new drug applications (NDAs), biologic license applications (BLAs) regulated by CDER, as well as supplements containing new clinical study reports.