ACTION: Request for public comments.

SUMMARY: The Administration on Children, Youth and Families, Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is requesting approval for a revision of a currently approved information collection, the Center for States Evaluation Ancillary Data Collection.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act 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 Evaluation of the Child Welfare Capacity Building Collaborative, Center for States is sponsored by the ACF Children's Bureau (CB). The purpose of this evaluation is to respond to a set of cross-cutting evaluation questions posed by the CB. This existing information collection is an ancillary part of a larger data collection effort being conducted for the evaluation of the Child Welfare Capacity Building Collaborative. This notice details a group of instruments that are specific only to the Center for States. The instruments focus on (1) evaluating an innovative approach to engaging professionals in networking and professional development through virtual expos, (2) understanding fidelity to and effectiveness of the Center's Capacity Building Model, (3) capturing information about individualized support to jurisdictions, and (4) enhancing the Center's support focused on equity and lived experience. To date, this data collection and resulting findings have been used to (a) assess satisfaction with service delivery and make adjustments to improve quality, (b) support professional development of child welfare professionals through improving the virtual expo experience, particularly during the pandemic, and (c) support provision of effective and high-quality individualized support to jurisdictions.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Annual average burden hours per response	Total annual burden hours
Child Welfare Virtual Expo Exit Survey	300	1	0.083	25
Child Welfare Virtual Expo Registration Form	3,000	1	0.05	150
Jurisdiction Lead Interview	40	1	1	40
Jurisdiction Lead Observation Debrief Protocol	25	1	0.25	6
Jurisdiction Lead Survey Related to Lived Experience	30	1	0.25	8
Outcomes of and Satisfaction with Tailored Services Survey Appended Items (Section 4)	40	1	0.05	2
Peer Group Focus Group Protocol	150	1	1	150
Total				381

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: Section 203 of section II: Adoption Opportunities of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5113).

Molly B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–10758 Filed 5–18–23; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by July 18, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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.

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

Submit written requests for single copies of the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on February 17, 2023 (88 FR 10354). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Baloxavir marboxil.
Belumosudil mesylate.
Belzutifan.
Bimatoprost.
Brincidofovir (multiple reference listed drugs).
Cabotegravir.
Casimersen.
Celecoxib; Tramadol hydrochloride.
Citric acid; Lactic acid; Potassium bitartrate.
Clobetasol propionate.
Defibrotide sodium.
Difelikefalin acetate.
Finerenone.
Givosiran sodium.
Inclisiran sodium.
Loxapine.
Maribavir.
Naloxone hydrochloride.
Odevixibat.
Pentoxifylline.
Piflufolastat f-18.
Sirolimus.
Voxelotor.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Azelastine hydrochloride; Fluticasone propionate.
Baloxavir marboxil.
Cabozantinib S-malate (multiple reference listed drugs).
Doxepin hydrochloride.
Fluticasone furoate.
Fluticasone propionate.
Formoterol fumarate.
Formoterol fumarate; Mometasone furoate.
Glycopyrrolate.
Glycopyrrolate; Indacaterol maleate.
Indacaterol maleate.
Ivacaftor.
Lidocaine.
Lithium carbonate (multiple reference listed drugs).
Mometasone furoate.
Paliperidone palmitate.
Rasagiline mesylate.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10710 Filed 5–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Substance Use Disorder Treatment and Recovery Loan Repayment Program and the Pediatric Specialty Loan Repayment Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 20, 2023.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Substance Use Disorder Treatment and Recovery Loan Repayment Program and the Pediatric Specialty Loan Repayment Program, OMB No. 0906–0058—Revision

Abstract: The Consolidated Appropriations Act, 2023 included $40,000,000 for the Substance Use Disorder Treatment and Recovery (STAR) Loan Repayment Program (LRP). This funding will allow HRSA to provide the repayment of education loans for individuals working in a full-time substance use disorder treatment job that involves direct patient care in either a Health Professional Shortage Area (HPSA) designated for Mental Health, or a county where the average drug overdose death rate exceeds the national average. The Further Consolidated Appropriations Act, 2022 and the Consolidated Appropriations Act, 2023 included $5,000,000 and $10,000,000, respectively, for HRSA to award eligible individuals through the Pediatric Specialty LRP. This funding will allow HRSA to provide the repayment of education loans to pediatric medical subspecialist, pediatric surgical specialist, and child and adolescent mental and behavioral health care providers working full-time in or serving a HPSA, medically underserved area (MUA), or medically underserved population (MUP). This information collection request adds the Pediatric Specialty LRP and relevant forms.

The Department of Health and Human Services agrees to make payment of up to $250,000 for the repayment of eligible educational loans in return for 6 years of service obligation through the STAR LRP, and up to $100,000 in return for 3 years of service obligation through the Pediatric Specialty LRP. The forms used by the STAR LRP and the Pediatric Specialty LRP include the following: the LRP Application, the Authorization for Disclosure of Loan Information form, the Privacy Act Release Authorization form, and the electronic Employment Verification form, if applicable. The forms collect information needed for selecting participants and repaying eligible educational loans.

Eligible disciplines for the STAR LRP and the Pediatric Specialty LRP include, but are not limited to physicians, psychologists, psychiatric nurses, marriage and facility therapists, social workers, counselors, and substance use disorder counselors. Additional providers that are exclusively eligible for the Pediatric Specialty LRP include pediatric medical subspecialty, pediatric surgical specialty, and child and adolescent mental and behavioral health care providers.

Eligible facilities or sites for the STAR LRP and Pediatric Specialty LRP programs include, but are not limited to: School-Based Clinics, Community Health Centers, Inpatient Programs/Rehabilitation Centers, Federally Qualified Health Centers, Centers for Medicare & Medicaid Services-approved Critical Access Hospitals, American Indian Health Facilities (Indian Health Service Facilities, Tribally-Operated 638 Health Programs, and Urban Indian Health Programs), inpatient