in support of the service referral responsibilities of the State Refugee Coordinators. Similar information for ORR's discretionary grants is currently made public.

DATES: *Comments due within 30 days of publication.* The Office of Management and Budget (OMB) is required to make a decision concerning 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.

SUPPLEMENTARY INFORMATION:

Description: This data collection requests RSS grantees and RSS Set Aside grantees to provide the agency name, city, state, website, and funding amount for each contracted sub-grantee.

The information will be used for national resource mapping pertaining to ORR RSS funding at the local level. Improved knowledge of all local providers is important to ORR's overall oversight of the program. In addition to RSS formula funding to states and state replacement agencies who then issue sub-awards to local providers, ORR also awards discretionary grants that directly fund local refugee service providers. This report will provide ORR a complete picture of the availability all ORR resources to assist newly arrived refugees at the local level increasing our ability to identify gaps or target areas of need.

Respondents: State governments and replacement designees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
RSS and RSS Set Aside Sub-grantee List	56	3	2	336	112

Estimated Total Annual Burden Hours: 112.

Authority: Refugee Act of 1980 [Immigration and Nationality Act, Title IV, Chapter 2 Section 412(e)] and 45 CFR 400.28.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–18307 Filed 8–24–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations

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 ''Environmental Impact Considerations.''

DATES: Submit either electronic or written comments on the collection of information by October 25, 2021.

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 October 25, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 25, 2021. 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–2012–N–0961 for ''Environmental Impact Considerations.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations

OMB Control Number 0910–0322—Extension

I. Background

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information ''Environmental Impact Considerations.'' The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting Agency action require the submission of a claim for categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. In § 25.15(a) and (d) (21 CFR 25.15(a) and (d)) the procedures for submitting to FDA a claim for a categorical exclusion are specified. Extraordinary circumstances (under 21 CFR 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) (21 CFR 25.40(a) and (c)) specifies the content requirements for EAs for non-excluded actions.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the Agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the Agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the Agency after the publication of the draft EIS, a copy or a summary of the comments received on the draft EIS, and the Agency's responses to the comments, including any revisions resulting from the comments or other information. When the Agency finds that no significant environmental effects are expected, the Agency prepares a finding of no significant impact.

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

II. Estimated Annual Reporting Burden for Human Drugs (Including Biologics in the Center for Drug Evaluation and Research)

Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 (21 CFR 25.30) or § 25.31 (21 CFR 25.31), or an EA under § 25.40. Annually, FDA receives approximately

5,503 INDs from 3,717 sponsors; 142 NDAs from 111 applicants; 3,285 supplements to NDAs from 516 applicants; 35 biologic license applications (BLAs) from 32 applicants; 777 supplements to BLAs from 89 applicants; 743 ANDAs from 239 applicants; and 11,438 supplements to ANDAs from 482 applicants. FDA estimates that it receives approximately 21,923 claims for categorical exclusions as required under § 25.15(a) and (d) and 13 EAs as required under § 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA. Based on recent numbers, we now estimate a total of 21,936 annual responses and 219,584 hours for human drugs (an increase of 6,489 responses and 62,088 hours).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and(d)	5,186	4.2273	21,923	8	175,384
25.40(a) and (c)	14	0.9285	13	3,400	44,200
Total					219,584

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

III. Estimated Annual Reporting Burden for Medical Devices

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approval applications (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 (21 CFR 25.34) or an EA under § 25.40. In 2020, FDA received an average of 62 claims (original PMAs and supplements) for categorical exclusions as required under § 25.15(a) and (d), and 0 EAs as required under § 25.40(a) and (c). FDA estimates that approximately 62 respondents will submit an average of 1 application for categorical exclusion annually. Based on information provided by sponsors, FDA estimates that it takes approximately 6 hours to prepare a claim for a categorical exclusion. Based on recent numbers, we now estimate a total of 62 annual responses and 372 hours for medical devices (an increase of 12 responses and 72 hours).

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR MEDICAL DEVICES [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	62	1	62	6	372

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

IV. Estimated Annual Reporting Burden for Biological Products, Drugs, and Medical Devices in the Center for Biologics Evaluation and Research

Under 21 CFR 601.2(a), BLAs as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of categorical exclusion under § 25.30 or § 25.32 (21 CFR 25.32) or an EA under § 25.40. Annually, FDA receives approximately 11 BLAs from 11 applicants, 1,080 BLA supplements to license applications from 160 applicants, 7,017 INDs from 2,087 sponsors, 1 NDA from 1 applicant, 16 supplements to NDAs from 6 applicants, 1 ANDA from 1 applicant, 3 supplements to ANDAs from 2 applicants, 1 PMA from 1 applicant, and 79 PMA supplements from 19 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it has received approximately 7,150 claims for categorical exclusion as required under § 25.15(a) and (d) annually and 4 EAs as required under § 25.40(a) and (c) annually. Therefore, FDA estimates that approximately 3,575 respondents will submit an average of 2 applications for categorical exclusion, and 4 respondents will submit an average of 1 EA. Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim of categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product. Based on recent numbers, we now estimate a total of 7,154 annual responses and 70,800 hours for biological products (an increase of 6,658 responses and 60,048 hours).

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	3,575	2	7,150	8	57,200
25.40(a) and(c)	4	1	4	3,400	13,600
Total					70,800

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

V. Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); supplemental NADAs and ANADAs (21 CFR 514.8(a)(1)); investigational new animal drug applications (INADs) and generic investigational new animal drug applications (JINADs) (21 CFR 511.1(b)(10)); and food additive petitions (21 CFR 571.1(c)) must contain a claim for categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA's Center for Veterinary Medicine has received approximately 1,140 claims for categorical exclusion as required under § 25.15(a) and (d) and 9 EAs as required under § 25.40(a) and (c). Assuming an average of 10 claims per respondent, FDA estimates that approximately 114 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that nine respondents will submit an average of one EA. FDA estimates that it takes sponsors/applicants approximately 3 hours to prepare a claim of categorical exclusion and an average of 2,160 hours to prepare an EA. Based on recent numbers, we now estimate a total of 22,860 hours for animal drugs (a decrease of 27,090 hours).

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	114	10	1,140	3	3,420
25.40(a) and (c)	9	1	9	2,160	19,440
Total					22,860

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

VI. Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements, premarket tobacco applications (PMTAs), substantial equivalence (SE), exemption from SE, and modified risk tobacco product applications (MRTPAs) must contain a claim for categorical exclusion or an EA. The majority of the EA burden for tobacco products is covered under already existing information collections. The burden for SEs is currently approved under OMB control number 0910–0673; the burden for PMTAs are currently approved under OMB control number 0910–0768; the burden for SE exemptions are currently approved under OMB control number 0910–0684.

FDA's estimates are based on actual report data from fiscal year (FY) 2018 to FY 2020. On average, FDA estimated it received approximately 14 MRTPAs from 14 respondents. Based on updated data for this collection, FDA estimates 14 EAs from 14 respondents. A total of 14 respondents will submit an average of one application for environmental assessment. Based on FDA's experience, previous information provided by potential sponsors, and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA. Based on recent MRTPA numbers, we now estimate a total of 14 annual responses and 1,120 hours for tobacco products (a decrease of 13 responses and 1,040 hours).

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	14	1	14	80	1,120

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

FDA estimates the burden for this information collection to be 30,315 annual responses, and 314,736 hours. These estimates reflect an overall increase of 13,463 responses and 94,078 hours. These adjustments are attributed to an increase in the number of responses the various centers in FDA have received over the last few years.

Dated: August 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18239 Filed 8–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1216]

Electronic Common Technical Document; Data Standards; Specifications for the Electronic Common Technical Document Validation Criteria

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are announcing the date that FDA will begin rejecting submissions which fail Electronic Common Technical Document (eCTD) validations 1306 or 1323 that have been raised to high validation errors as described in the ''Specifications for eCTD Validation Criteria.''