• *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–N–4000 for ''Framework for a Real-World Evidence Program; Availability.'' 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.

• 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–2500, *dianne.paraoan@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *stephen.ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is establishing a public docket to collect comments on its ''Framework for a Real-World Evidence Program.'' Section 3022 of the Cures Act amended the FD&C Act to add section 505F, Utilizing real world evidence (21 U.S.C. 355g). This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help to support or satisfy postapproval study requirements. This section also requires FDA publish a framework for that program. In addition to drug and biological products approved under section 505(c) of the FD&C Act, FDA is also applying this framework to biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

The statute directs that the framework for the RWE program include information describing sources of RWE, gaps in data collection activities, standards and methodologies for collecting and analyzing RWE, and priority areas, remaining challenges, and potential pilot opportunities to address the overarching Cures Act requirements. To help meet a requirement in the Cures Act for consultation in developing the program framework, on September 13, 2017, through its cooperative agreement with the Duke Margolis Center for Health Policy, FDA convened a public meeting that explored the use of RWE for regulatory decisions. Representatives from industry, academia, and patient advocacy groups discussed, among other things, opportunities and challenges associated with applying real-world data and RWE, the evidence derived from that data, to demonstrate product effectiveness, including data acquisition, study design, and analytic methods necessary to establish causal inference. The workshop helped to inform FDA's RWE framework. FDA will continue to consult stakeholders through public-private partnerships, public workshops, and demonstration projects as it implements its RWE program.

II. Electronic Access

Persons with access to the internet may obtain the ''Framework for the Real-World Evidence Program'' at *https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/21stCenturyCuresAct/ucm562475.htm.*

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26546 Filed 12–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

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: Fax written comments on the collection of information by January 7, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0322. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 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) 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.

In the **Federal Register** of June 7, 2018 (83 FR 26477), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA related comment was received.

(Comment) One commenter requested that FDA should categorically exclude all categories of SE applications from the EA requirement.

(Response) FDA appreciates this comment. We note, however, that any action to establish a categorial exclusion would need to be undertaken through a notice and comment rulemaking procedure.

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 or § 25.31, or an EA under § 25.40. Annually, FDA receives approximately 3,687 INDs from 2,456 sponsors; 140 NDAs from 116 applicants; 3,192 supplements to NDAs from 443 applicants; 28 biologic license applications (BLAs) from 22 applicants; 464 supplements to BLAs from 52 applicants; 1,152 ANDAs from 248 applicants; and 6,774 supplements to ANDAs from 384 applicants. FDA estimates that it receives approximately 15,437 claims for categorical exclusions as required under § 25.15(a) and (d) and 10 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.

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)	3,724	4.1453	15,437	8	123,496
25.40(a) and (c)	10	1	10	3,400	34,000
Total					157,496

[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 approvals (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 2017, FDA received an average of 50 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 50 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.

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)	50	1	50	6	300

[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 or an EA under § 25.40. Annually, FDA receives approximately 34 BLAs from 18 applicants, 801 BLA supplements to license applications from 156 applicants, 345 INDs from 256 sponsors, 1 NDA from 1 applicant, 26 supplements to NDAs from 8 applicants, 1 ANDA from 1 applicant, 1 supplement to ANDAs from 1 applicant, 8 PMAs from 3 applicants, and 33 PMA supplements from 16 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA has received approximately 481 claims for categorical exclusion as required under § 25.15(a) and (d) annually and 2 EAs as required under § 25.40(a) and (c) annually. Therefore, FDA estimates that approximately 247 respondents will submit an average of 2 applications for categorical exclusion and 2 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.

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)	247	2	494	8	3,952
25.40(a) and (c)	2	1	2	3,400	6,800
Total					10,752

[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); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs) and generic investigational new animal drug applications (JINADs), and 21 CFR 571.1(c) food additive petitions 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 810 claims for categorical exclusion as required under § 25.15(a) and (d) and 22 EAs as required under § 25.40(a) and (c). Assuming an average of 10 claims per respondent, FDA estimates that approximately 81 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that 22 respondents will submit an average of 1 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.

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)	81	10	810	3	2,430
25.40(a) and (c)	22	1	22	2,160	47,520
Total					49,950

[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 (PMTAs), SEs, Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion or an EA. After further review, the agency has concluded that the majority of the EA burden for tobacco products

is covered under already existing information collections. To avoid double counting, the agency has removed the burden which is approved under other FDA information collections. The burden for SEs are 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) 2015 to FY 2017, on average FDA estimated it received approximately 27 modified risk tobacco product applications (MRTPAs) from 27 respondents. Based on updated data for this collection, FDA estimates 27 EAs from 27 respondents. A total of 27 respondents will submit an average of 1 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.

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)	27	1	27	80	2,160

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

The Estimated Annual Reporting Burden for Human Foods is no longer a part of this information collection. The burden has now been incorporated into OMB control number 0910–0541.

Our estimated burden for the information collection reflects an overall decrease of 10,566 hours (currently approved 231,224) and a corresponding decrease of 11,364 annual responses (currently approved 15,527). The new estimated totals are 220,658 hours and 4,163 annual responses. We attribute this adjustment to the removal of the majority tobacco burden from this collection, and the number of EA submissions we received since the last extension.

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26556 Filed 12–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Family-to-Family Health Information Center Feedback Surveys, OMB Number: 0906–xxxx–New

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

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.

DATES: Comments on this ICR must be received no later than January 7, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Family-to-Family Health Information Center Feedback Surveys, *OMB Control Number:* 0906–xxxx–New.

Abstract: The Family-to-Family Health Information Center (F2F HIC) program is authorized by the Social Security Act, Title V, § 501(c) (42 U.S.C. 701(c)), as amended by § 50501 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123). The goal of the F2F HIC program is to promote optimal health for children and youth with special health care needs (CYSHCN) by facilitating their access to an effective health delivery system and by meeting the health information and support needs of families of CYSHCN and the professionals who serve them. F2F HICs are staffed by families of CYSHCN who have first-hand knowledge using health care services and programs. With this experience, these staff are uniquely positioned to provide support to other CYSHCN families and help other families like theirs navigate an often complex and confusing health care and social service system. They also serve as mentors and as a reliable source of health care information to other families.

During Fiscal Years (FY) 2003 to 2017, HRSA's Maternal and Child Health Bureau (MCHB) awarded approximately $4.9 million per FY in grants to support 51 F2F HICs in each of the 50 states and the District of Columbia. In FY 2017, 49 centers that reported data served and trained over 184,000 families and approximately 85,500 health professionals. For FYs 2018 and 2019, HRSA MCHB will award approximately $6 million per FY to support 59 F2F HICs: One each in the 50 states and the District of Columbia, 1 each in the 5 U.S. Territories (American Samoa, Guam, Puerto Rico, the Northern Mariana Islands and the U.S. Virgin Islands), and 3 to serve American Indians/Alaska Natives.

HRSA has developed feedback surveys to determine the extent to which F2F HICs provide service to families of CYSHCN and health professionals who serve such families. Each F2F HIC will administer the surveys and report data back to HRSA. Survey respondents will be asked to answer questions about how useful they found the information, assistance, or resources received from the F2F HICs. The purpose of this notice is to solicit comments regarding the proposed feedback surveys and the F2F HIC grant recipient activity instructions form.