collection, which is being conducted to evaluate the campaign.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent type and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Venue Owners and Managers	660	1	660	0.083 (5 minutes)	55
General Population: Pilot test of Procedures in Bars.	27	1	27	0.083 (5 minutes)	2
General population—outcome screener (in person).	11,239	1	11,239	0.083 (5 minutes)	933
General population—outcome screener (social media).	3,539	1	3,539	0.083 (5 minutes)	294
LGBT young adults outcome baseline (social media).	263	1	263	0.5 (30 minutes)	132
LGBT young adults outcome baseline (in person).	788	1	788	0.5 (30 minutes)	394
LGBT young adults outcome followup questionnaire (social media).	1,752	1	1,752	0.667 (40 minutes)	1,169
LGBT young adults outcome followup questionnaire (in person).	5,378	1	5,378	0.667 (40 minutes)	3,587
Totals					6,566

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

To accommodate the additional waves of data collection, FDA requests approval to increase the number of burden hours under the existing control number. The previous number of approved responses was 53,967 (17,989 annualized), and the previous burden was 14,031 hours (4,677 annualized). The fifth and sixth followups add 23,478 responses (7,826 annualized), which include responses to new venues assessments, screening questionnaires, and the followup questionnaires, for a total of 7,074 additional burden hours (2,357 annualized). Removing the media tracking component deducts 6,507 responses (2,169 annualized) and 1,413 burden hours (471 annualized). The totals for the entire evaluation study are increasing by 16,971 responses (5,657 annualized) and 5,661 hours (1,887 annualized) for a new total of 70,938 responses (23,646 annualized) and 19,692 burden hours (approximately 6,566 annualized).

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26555 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–2018–N–4000]

Framework for a Real-World Evidence Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on a framework created by the Center for Drug Evaluation and Research and the Center for Biologic Evaluation and Research for implementing a program to evaluate the potential use of real-world evidence (RWE) in regulatory decision making. This framework is entitled ''Framework for the Real-World Evidence Program.'' The 21st Century Cures Act (Cures Act) was enacted on December 13, 2016, and requires that FDA establish a framework for implementing a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to help support or satisfy postapproval study requirements. FDA has created this framework to satisfy the Cures Act mandate and is establishing a docket to receive public comments.

DATES: Submit either electronic or written comments on the draft document by February 5, 2019 to ensure that the Agency considers your comment before it begins work to implement the program.

ADDRESSES: You may submit comments 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–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