each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of Collection	OMB control No.	Date approval expires
Agreement for Shipment of Devices for Sterilization	0910–0131	9/30/2022
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910–0339	9/30/2022
Clinical Laboratory Improvement Amendments Waiver Applications	0910–0598	9/30/2022
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products	0910–0650	9/30/2022
Tobacco Health Document Submission	0910–0654	9/30/2022
Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence Requirements for Tobacco Products	0910–0673	9/30/2022
Exemptions From Substantial Equivalence Requirements for Tobacco Products	0910–0684	9/30/2022
Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts and 351(k) Biologics License Applications in Biosimilars User Fee Act	0910–0746	9/30/2022
Medical Device Accessories	0910–0823	9/30/2022

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24263 Filed 11–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3768]

Best Practices in Drug and Biological Product Postmarket Safety Surveillance for Food and Drug Administration Staff; Draft Document; Availability; Establishment of Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on a draft document that details best practices for drug safety surveillance entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff.'' The 21st Century Cures Act (Cures Act) was enacted on December 13, 2016, and requires that FDA make publicly available on its internet website best practices for drug safety surveillance activities. The draft document sets forth risk-based principles by which FDA conducts ongoing postmarketing safety surveillance for drug and biological products to address the Cures Act requirements. FDA is seeking public comment on the draft best practices in drug and biological product postmarket safety surveillance.

DATES: Submit either electronic or written comments on the draft document by January 6, 2020 to ensure that the Agency considers your comment on this draft document before it begins work on the final version.

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–2019–N–3768 for ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff.'' 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: Eileen Wu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3472, Silver Spring, MD 20993–0002, 301–796–2345, *eileen.wu@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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is establishing a public docket to collect comments on a draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff.'' Title IX, section 915 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) added a new section 505(r) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(r)), requiring FDA to prepare a summary analysis of the adverse drug reaction reports received for a drug by 18 months after approval or after use of the drug by 10,000 individuals, whichever is later. The analysis includes identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number.

The Cures Act (Pub. L. 114–255) was enacted on December 13, 2016, and has the goal of advancing medical product innovation, as well as ensuring patient access to safe and effective treatments as soon as possible. Section 3075 of the Cures Act amended section 505(r)(2)(D) of the FD&C Act to eliminate the requirement for summary analyses for drugs as required by FDAAA. In place of the summary analyses, section 3075 amended section 505(r)(2)(D) of the FD&C Act to include the requirement that FDA make publicly available on its internet website best practices for drug safety surveillance activities for drugs approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act).

Section 3075 of the Cures Act also amended section 505(k)(5) of the FD&C Act to strike ''bi-weekly screening'', as required by FDAAA, and insert ''screenings''; it also added the requirement that FDA make publicly available on its internet website guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System.

The draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff'' sets forth risk-based principles by which FDA conducts ongoing postmarketing safety surveillance for drug and biological products to address the Cures Act requirements. Although section 3075 of the Cures Act only references drugs approved under section 505 of the FD&C Act or section 351 of the PHS Act, the draft document additionally provides a high-level discussion regarding other products, including over-the-counter monograph, compounded, and homeopathic drug products. The draft document also includes a high-level overview of other data sources, tools, and methods, as well as drug safety surveillance activities that extend beyond use of the Adverse Event Reporting System (and its successors). These additional topics are included to provide context and a general overview of FDA's safety surveillance process. FDA is seeking public comment on the draft best practices document before it begins work on the final version, which will be made publicly available.

II. Electronic Access

Persons with access to the internet may obtain the draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff'' at *https://www.fda.gov/media/130216/download.*

Dated: November 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24332 Filed 11–6–19; 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: Healthy Start Evaluation and Quality Improvement, OMB No. 0915–0338—Revision

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 has 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 should be received no later than December 9, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

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

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Quality Improvement. OMB No. 0915–0338—Revision.

Abstract: The National Healthy Start Program, funded through HRSA's Maternal and Child Health Bureau (MCHB), has the goal of reducing racial and ethnic disparities in infant mortality and other adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and since then has expanded to 101 grantees serving communities in 34 states, Washington, DC, and Puerto