notice of opportunity for a hearing on February 28, 2022. Mr. Zipperer failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Kenneth Zipperer has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Zipperer is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Zipperer is a prohibited act.

Any application by Mr. Zipperer for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–1156 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15795 Filed 7–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0810]

Conducting Remote Regulatory Assessments—Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Conducting Remote Regulatory Assessments—Question and Answers.'' FDA is issuing the draft guidance to describe the Agency's current thinking regarding its use of remote regulatory assessments (RRAs) in order to increase industry's understanding of RRAs and facilitate FDA's process for conducting RRAs. FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs and help maximize compliance of FDA-regulated products. This draft guidance provides answers to frequently asked questions regarding what RRAs are, when and why FDA may use them, and how FDA may conduct them, among others.

DATES: Submit either electronic or written comments on the draft guidance by September 23, 2022 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–2022–D–0810 for ''Conducting Remote Regulatory Assessments; Questions and Answers; Guidance 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 Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by email by emailing ORA at *orapolicystaffs@fda.hhs.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christopher Henderson, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857, *Christopher.Henderson@fda.hhs.gov,* 240–402–8186; or Ben Firschein, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, *Ben.Firschein@fda.hhs.gov,* 240–402–8186.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Conducting Remote Regulatory Assessments—Questions and Answers.'' FDA is issuing the draft guidance to describe the Agency's current thinking regarding its use of RRAs in order to help increase industry's understanding of RRAs, thereby facilitating FDA's process for conducting remote assessments. RRAs include requests for records and other information for FDA review and interactive evaluations of an FDA-regulated establishment or product with the use of, for example, livestreaming video. RRAs can be either voluntary or mandated. FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs, and help maximize compliance with applicable FDA requirements, for all types of FDA-regulated products.

For example, during the Coronavirus Disease 2019 (COVID–19) pandemic, FDA has used RRAs to inform approval and licensing decisions, verify corrective actions for establishments with an acceptable compliance status, and gain compliance insight into establishments that FDA has been unable to inspect. This experience has identified significant benefits of using RRAs to FDA, regulated industry, and the public. For these and other reasons, FDA is issuing this draft guidance to describe its intention to, when appropriate, continue to use RRAs outside of the COVID–19 public health emergency and for all FDA-regulated product types.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Conducting Remote Regulatory Assessments.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

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

III. Electronic Access

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

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15812 Filed 7–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request: 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 23, 2022.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Teen Pregnancy Prevention Fiscal Year 2020/2021 Tier 1 and Tier 2 Implementation Study.

Type of Collection: New collection.

OMB No. 0990–NEW–Office of Population Affairs.

Abstract: The Office of Population Affairs (OPA), U.S. Department of Health and Human Services (HHS) is requesting 2 years of approval by OMB on a new collection. The Teen Pregnancy Prevention (TPP) Tier 1 and Tier 2 Implementation Study will document how 75 grantees funded in 2020 and 2021 are implementing their grant strategies to reduce rates of teen pregnancy and sexually transmitted infections in their selected communities or priority areas. OPA anticipates that grantees will employ diverse strategies working with partner organizations within communities to implement their teen pregnancy prevention projects. To document approaches and experiences of each grantee, a lead staff member in each grantee organization and up to one other staff member will be interviewed during an in-person or virtual site visit. Up to two staff members from key grantee partner organizations will be interviewed for 31 of the 62 Tier 1 grantees and all 13 Tier 2 grantees.