III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15823 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–2021–N–1156]

Kenneth Zipperer: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Kenneth Zipperer for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Zipperer was convicted of one felony count under Federal law relevant to these debarment proceedings for mail fraud. The factual basis supporting Mr. Zipperer's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Zipperer was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 30, 2022 (30 days after receipt of the notice), Mr. Zipperer had not responded. Mr. Zipperer's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable July 25, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On September 9, 2021, Mr. Zipperer was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Western District of Wisconsin, when the court entered judgment against him for two offenses, one of which is relevant to these debarment proceedings: the offense of mail fraud, in violation of 18 U.S.C. 1341. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Mr. Zipperer acknowledged in his plea and sentencing hearing on September 9, 2021, that he owned and operated Zipperer Financial LLC where he worked as an insurance broker selling Medicare insurance policies to elderly individuals. Mr. Zipperer imported, via U.S. mail, foreign-sourced prescription drugs from an internet pharmacy company in India using the website ''*www.alldaychemist.com.*'' The packages mailed from this pharmacy contained the return address of Derric Wood in Delhi, India, and Mr. Zipperer had these packages shipped to a P.O. Box he rented for Zipperer Financial LLC. Mr. Zipperer imported many of the foreign-sourced prescription drugs in wholesale quantities and broke down the bulk shipments and repackaged them into retail quantities for his individual clients. Mr. Zipperer distributed many of these foreign-sourced prescription medications to his clients in person, though he had no valid wholesale distribution license, pharmacy license, or license to prescribe prescription drugs.

Further, as Mr. Zipperer acknowledged in his plea and sentencing hearing on September 9, 2021, the prescription drugs Mr. Zipperer distributed to his clients were misbranded because they were foreign-sourced versions of various prescription drugs that were not approved by FDA for use in the United States and were dispensed to consumers without a valid prescription of a practitioner licensed by law to administer such drugs. The drugs were therefore misbranded because they did not contain adequate directions for use. Mr. Zipperer imported these misbranded prescription drugs in boxes containing customs declaration forms affixed outside the box that falsely declared that the contents were personal supply medications.

As a result of this conviction, FDA sent Mr. Zipperer, by certified mail, on February 14, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Zipperer's felony conviction for mail fraud, in violation of 18 U.S.C. 1341, was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported misbranded prescription drugs and then distributed those drugs, unlawfully, to consumers. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Zipperer's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Zipperer of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Zipperer received the proposal and

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]

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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