guidance is intended to assist interested parties (including prospective drug product applicants, drug product applicants, and approved application holders) in utilizing the Orange Book. This guidance provides answers to commonly asked questions FDA has received from interested parties regarding the Orange Book.

The Orange Book identifies drug products approved by FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and related patent and exclusivity information. The main criteria for the inclusion of a drug product in the Orange Book are that the drug product is the subject of an approved application and that FDA has not determined the drug product to have been withdrawn from sale for safety or effectiveness reasons. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to State health agencies, prescribers, and pharmacists to promote public education on drug product selection and to foster containment of healthcare costs.

This guidance provides answers to questions that have been received by FDA staff that manage the Orange Book. The questions and answers cover the following topics: general inquiries about the content and format of the Orange Book, petitioned abbreviated new drug applications, the movement of drug products between different sections in the Orange Book, and patent listings.

This guidance finalizes the draft guidance entitled ''Orange Book—Questions and Answers'' issued on June 1, 2020 (85 FR 33167). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include minor clarifying revisions (including revisions to reflect the Orange Book Transparency Act of 2020 enacted on January 5, 2021) (Pub. L. 116–290).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Orange Book—Questions and Answers.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The following collections of information have been approved under OMB control number 0910–0001: (1) 21 CFR 314.50(a) through (f), (i), (h), and (k); (2) 21 CFR 314.53 for new drug application (NDA) submissions; (3) amendments to NDA submissions; (4) supplements to NDA submissions to FDA using Forms FDA 3542 (Patent Information Submitted Upon and After Approval of an NDA or Supplement) and 3542a (Patent Information Submitted With the Filing of an NDA, Amendment, or Supplement); and (5) 21 CFR 314.94.

In addition, the FDA Reauthorization Act of 2017 (Pub. L. 115–52) added section 506I to the FD&C Act (21 U.S.C. 356i), which imposes marketing status reporting requirements for notification of withdrawal from sale, notification of drugs not available for sale, and reports on marketing status. The collections of information regarding 506I notifications described in FDA's guidance entitled ''Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act'' have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, 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. 2022–15831 Filed 7–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2040; FDA–2020–E–2041; and FDA–2020–E–2051]

Determination of Regulatory Review Period for Purposes of Patent Extension; VUMERITY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VUMERITY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 23, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 23, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 23, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 23, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 Nos. FDA–2020–E–2040; FDA–2020–E–2041; and FDA–2020–E–2051 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; VUMERITY.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, VUMERITY (diroximel fumarate). VUMERITY is indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Subsequent to this approval, the USPTO received a patent term restoration application for VUMERITY (U.S. Patent Nos. 8,669,281; 9,090,558; 10,080,733) from Alkermes Pharma Ireland Limited, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 5, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VUMERITY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VUMERITY is 1,944 days. Of this time, 1,623 days occurred during the testing phase of the regulatory review period, while 321 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 5, 2014. The applicant claims July 31, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 5, 2014, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 13, 2018. FDA has verified the applicant's claim that the new drug application (NDA) for VUMERITY (NDA 211855) was initially submitted on December 13, 2018.

3. *The date the application was approved:* October 29, 2019. FDA has verified the applicant's claim that NDA 211855 was approved on October 29, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 40 days of patent term extension.

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