application became effective was on October 3, 2008.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* August 17, 2017. FDA has verified the applicants' claim that the biologics license application (BLA) for CRYSVITA (BLA 761068) was initially submitted on August 17, 2017.

3. *The date the application was approved:* April 17, 2018. FDA has verified the applicants' claim that BLA 761068 was approved on April 17, 2018.

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 the applications for patent extension, these applicants seek 5 days, 1,168 days, or 501 days, respectively, 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: November 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25821 Filed 11–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1614]

Tzvi Lexier: 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 Tzvi Lexier for a period of 10 years from importing any drug into the United States. FDA bases this order on a finding that Mr. Lexier was convicted, as defined in the FD&C Act, of one felony count under Federal law for conspiracy to smuggle into and distribute within the United States misbranded drugs and one felony count under Federal law for unlicensed wholesale distribution of prescription drugs. The factual basis supporting both felony convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lexier was given notice of the proposed debarment and, in accordance with the FD&C Act, was given an opportunity to request a hearing to show why he should not be debarred. As of August 2, 2019 (30 days after receipt of the notice), Mr. Lexier had not responded. Mr. Lexier'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 November 29, 2019.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857 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 January 18, 2019, Mr. Lexier was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty and entered judgment against him for the offenses of conspiracy in violation of 18 U.S.C. 371 and unlicensed wholesale distribution of prescription drugs in violation of section 301(t) of the FD&C Act (21 U.S.C. 331(t)).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: As contained in the Stipulation of Facts incorporated into the Plea Agreement, filed on October 25, 2018, from on or about April 2011 to December 2014, Tzivi Lexier conspired with certain other named individuals to smuggle into and distribute within the United States, on multiple occasions, misbranded drugs. During this time, Mr. Lexier served as a principal of SB Medical and TC Medical. In that role, he coordinated the supply of drugs from foreign countries ultimately intended for the illegal importation into and sale inside the United States. The misbranded and unapproved prescription drugs smuggled and sold in the United States by the conspiracy include: Aclasta; Mabthera; and Bonviva, as well as foreign, unapproved versions of FDA-approved drug products Actemra; Botox; Botox Cosmetic; Dysport; Lucentis; Orencia; Prolia; Remicade; and, Zometa.

As a result of this conviction, FDA sent Mr. Lexier by certified mail on June 24, 2019, a notice proposing to debar him for two consecutive 5-year periods (10 years) 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. Lexier's felony convictions for conspiracy in violation of 18 U.S.C. 371 and unlicensed wholesale distribution of prescription drugs in violation of section 301(t) of the FD&C Act were for conduct relating to the importation into the United States of any drug or controlled substance because he conspired with others to smuggle into and distribute within the United States, on multiple occasions, misbranded drugs. 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. Lexier's offenses, concluded that each of these felony offenses independently warranted a five-year period of

debarment, and proposed that these debarment periods be served consecutively under section 306(c)(2)(A)(iii).

The proposal informed Mr. Lexier of the proposed debarment and offered Mr. Lexier 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. Lexier received the proposal and notice of opportunity for a hearing on July 1, 2019. Mr. Lexier 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. Lexier has been convicted of two felony counts under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that each offense should be accorded a debarment period of 5 years. Under section 306(c)(2)(A)(iii) of the FD&C Act, in the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively. FDA has concluded that the 5-year period of debarment for each of the two offenses of conviction needs to be served consecutively, resulting in a total debarment period of 10 years.

As a result of the foregoing finding, Mr. Lexier is debarred for a period of 10 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, 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. Lexier is a prohibited act.

Any application by Mr. Lexier for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–1614 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies. 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 *http://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25824 Filed 11–27–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–2595]

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

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 OZEMPIC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 28, 2020. 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 May 27, 2020. 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 January 28, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 28, 2020. 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 No.FDA–2018–E–2595 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; OZEMPIC.'' 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.

- 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