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 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product ENSPRYNG (satralizumab-mwge). ENSPRYNG is indicated for the treatment of neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive. Subsequent to this approval, the USPTO received patent term restoration applications for ENSPRYNG (U.S. Patent Nos. 8,562,991; 10,022,319; 10,662,245) from Genentech, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ENSPRYNG 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 ENSPRYNG is 2,495 days. Of this time, 2,128 days occurred during the testing phase of the regulatory review period, while 367 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 (21 U.S.C. 355(i)) became effective:* October 18, 2013. The applicant claims October 20, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 18, 2013, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

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 15, 2019. FDA has verified the applicant's claims that the biologics license application (BLA) for ENSPRYNG (BLA 761149) was initially submitted on August 15, 2019.

3. *The date the application was approved:* August 14, 2020. FDA has verified the applicant's claims that BLA 761149 was approved on August 14, 2020.

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 81 days, 563 days, or 1,428 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 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14930 Filed 7–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. FDA–2021–N–1322]

Kris A. Hampton-Bey II: 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 Kris A. Hampton-Bey II 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. Hampton-Bey II engaged in a pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Mr. Hampton-Bey II 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 May 8, 2022 (30 days after receipt of the notice), Mr. Hampton-Bey II had not responded. Mr. Hampton-Bey II'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 13, 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)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import adulterated or misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer) that are not designated in an entry in an authorized electronic data interchange system as products regulated by FDA.

After an investigation, FDA discovered that Mr. Hampton-Bey II has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action, described in further detail below, were intercepted by FDA at either the Newark or Chicago International Mail Facilities (IMF) and were addressed to Mr. Hampton-Bey II at an address connected to him.

On or about March 11, 2019, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 550 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and because the article was determined to lack adequate directions for use. The product was refused entry on April 8, 2019.

On or about June 25, 2019, Mr. Hampton-Bey II offered for import two parcels intercepted and processed by FDA at the Chicago IMF and which were addressed to him. FDA determined that the product contained in the first parcel was 850 tablets of Sildenafil Tabs 100 MG and was a misbranded drug because the article was determined to lack adequate directions for use and because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. FDA determined that the product contained in the second parcel was 850 tablets of Sildenafil 100 MG Tabs and was a misbranded drug because the article was determined to lack adequate directions for use and because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. Both products were refused entry on July 17, 2019.

On or about August 19, 2019, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 900 tablets of Sildenafil Tabs 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and because the article was determined to lack adequate directions for use. The product was refused entry on September 12, 2019.

On or about December 28, 2020, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of Sildenafil Tabs 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and because the article was determined to be a drug that was not included in a list required by section 510(j) of the FD&C Act (21 U.S.C. 360(j)). The product was refused entry on January 19, 2021.

On or about December 29, 2020, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. The product was refused entry on January 21, 2021.

On or about December 29, 2020, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil citrate and was a misbranded drug because the article was determined to lack adequate directions for use. The product was refused entry on January 22, 2021.

On or about January 5, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil and was a misbranded drug because the article was determined to lack adequate directions for use and because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. The product was refused entry on February 5, 2021.

On or about January 6, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of Sildenafil Tablets 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and because the article had been determined to lack adequate directions for use. The product was refused entry on February 1, 2021.

On or about January 7, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the first product contained in this parcel was 850 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and because the article had been determined to lack adequate directions for use. FDA determined that the second product contained in this parcel was 10 tablets of sildenafil citrate tablets and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and because the article had been determined to lack adequate directions for use. Both products were refused entry on February 3, 2021.

On or about March 4, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 87 tablets of sildenafil tablets and was a misbranded drug because the article was determined: (1) to be a prescription drug but did not include the symbol ''Rx only'' on its label; (2) not to bear a label containing the name and place of business of the manufacturer, packer, or distributor; (3) to be a drug that was not included in a list required by section 510(j) of the FD&C Act; and (4) to be a drug that was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. The

product was refused entry on April 5, 2021.

On or about March 17, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Newark IMF and which was addressed to him. FDA determined that the product contained in this parcel was 364 tablets of BEGMA–100 Sildenafil Citrate Tablets 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. The product was refused entry on April 23, 2021.

On or about March 24, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. The product was refused entry on April 19, 2021.

On or about April 20, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 800 tablets of Sildenafil 100 MG Tablets and was a misbranded drug because the article was determined to be a drug that was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on May 11, 2021.

As a result of this pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Mr. Hampton-Bey II, by certified mail on April 4, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States.

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. Hampton-Bey II's pattern of conduct and concluded that his conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Hampton-Bey II of the proposed debarment and offered him an opportunity to request a hearing, providing 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. Hampton-Bey II received the proposal and notice of opportunity for a hearing on April 8, 2022. Mr. Hampton-Bey II 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)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Kris A. Hampton-Bey II has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct 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. Hampton-Bey II is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (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 by, with the assistance of, or at the direction of Mr. Hampton-Bey II is a prohibited act.

Any application by Mr. Hampton-Bey II for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–1322 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 *http://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 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14899 Filed 7–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2275]

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

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 BLENREP 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 biological 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 12, 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 9, 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 12, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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,