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–2024–D–5601 for ''E6(R3) Good Clinical Practice: Annex 2.'' 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)).

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Amy Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6334, Silver Spring, MD 20993–0002, *Amy.Chi@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 30, 2024 (89 FR 106519), FDA published a notice of availability with a 60-day period to provide comments on the draft guidance entitled ''E6(R3) Good Clinical Practice: Annex 2.'' The draft guidance provides guidance on good clinical practices for trial design and conduct, with a focus on trials with decentralized and pragmatic elements as well as trials that utilize real-world data. Since the original E6 guidance was published in 1996, clinical trials have evolved significantly with new designs and technological innovations. Annex 2 provides additional considerations to the previously published draft guidance entitled ''E6(R3) Good Clinical Practice (GCP),'' which includes a Principles document and Annex 1. This draft guidance, entitled ''E6(R3) Good Clinical Practice: Annex 2,'' is intended to be read and implemented with E6(R3) Principles and Annex 1.

Interested persons were originally given until February 28, 2025, to submit comments to the docket. FDA has received requests to extend the comment period to allow sufficient time to develop and submit meaningful comments. FDA has considered the requests and is reopening the comment period until March 31, 2025. The Agency believes that reopening the comment period until March 31, 2025, allows adequate additional time for interested persons to submit comments.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04026 Filed 3–12–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3359]

Harpreet Singh: 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 Harpreet Singh for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding Mr. Singh was convicted of multiple felony offenses, which serve as the basis for this debarment, that are conspiracy to possess with intent to distribute cathinone, tapentadol, tramadol, and carisoprodol; one felony count under Federal law for fraudulent importation and transportation of goods; one felony count under Federal law for conspiracy to launder money; and one felony count under Federal law for conspiracy to obstruct justice. The factual basis supporting Mr. Singh's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Singh 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 November 20, 2024 (30 days after receipt of the notice), Mr. Singh had not responded. Mr. Singh'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 March 13, 2025.

ADDRESSES: Any application by Mr. Singh for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your

application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov*.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2024–N–3359. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, at 240–402–8743, or *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 May 21, 2024, Mr. Singh was convicted as defined in section 306(l)(1) of the FD&C Act in the United States District Court for the Eastern District of New York when the court accepted his plea of guilty and entered judgment against him for multiple felony offenses that are conspiracy to possess with intent to distribute cathinone, tapentadol, tramadol, and carisoprodol, in violation of 21 U.S.C. 846 and 841(b)(1)(C); one felony count under Federal law for fraudulent importation and transportation of goods in violation of 18 U.S.C. 545; one felony count under Federal law for conspiracy to launder money in violation of 18 U.S.C. 1956(a) and 1956(h); and one felony count under Federal law for conspiracy to obstruct justice in violation of 18 U.S.C. 1512(c) and 1512(k). The underlying facts supporting the conviction are as follows: as contained in the Information from his case, between January 2017 and September 2019, Mr. Singh knowingly, intentionally and with intent to defraud the United States, smuggled, and clandestinely introduced and attempted to smuggle and clandestinely introduced into the United States misbranded drugs, which should had been invoiced, and made out and passed, and attempted to pass, through the customhouse one or more false, forged and fraudulent invoices, and other documents and papers; and knowingly, intentionally and fraudulently imported and brought into the United States merchandise contrary to law, and receive, conceal, buy, sell and facilitate the transportation, concealment and sale of the misbranded drugs, knowing that the drugs to have been imported and brought into the United States contrary to law. In addition, Mr. Singh together with others, did knowingly and intentionally conspire to distribute and possess with intent to distribute one or more controlled substances that are cathinone, a schedule I controlled substance; tapentadol, a schedule II controlled substance; and tramadol and carisoprodol, schedule IV controlled substances. Also, together with others, Mr. Singh knowingly and intentionally conspired: (a) to conduct one or more financial transactions affecting interstate and foreign commerce, to wit: interstate and foreign transfers of funds and payments of Federal Express bills, which transactions in fact involved the proceeds of specified unlawful activity, to wit: the crimes charged in counts one and two of the Information, knowing that the property involved in the financial transactions represented the proceeds of some form of unlawful activity, with the intent to promote the carrying on of specified unlawful activity, in violation of 18 U.S.C. 1956(a)(1)(A)(i); and (b) to conduct one or more financial transactions affecting interstate and foreign commerce, to wit: interstate and foreign transfers of funds and payments of Federal Express bills, which transactions in fact involved the proceeds of the crimes charged in counts one and two of the Information, knowing that the property involved in the financial transactions represented the proceeds of some form of unlawful activity, and knowing that the transactions were designed in whole and in part to conceal and disguise the nature, location, source, ownership and control of the proceeds of specified unlawful activity, in violation of 18 U.S.C. 1956(a)(1)(B)(i).

As further contained in the Information from Mr. Singh's case, between approximately August 2019 and September 2019, Mr. Singh, together with others, knowingly and intentionally conspired to corruptly alter, destroy, mutilate and conceal records, documents and other objects

with the intent to impair the objects' integrity and availability for use in an official proceeding, to wit: a grand jury investigation in the Eastern District of New York, in violation of 18 U.S.C. 1512(c)(1) and 1512(k).

FDA sent Mr. Singh, by certified mail, on October 3, 2024, a notice proposing to debar him for a 10-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. Singh's felony convictions under Federal law for conspiracy to possess with intent to distribute cathinone, tapentadol, tramadol, and carisoprodol, fraudulent importation and transportation of goods, conspiracy to launder money, and conspiracy to obstruct justice, was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Singh illegally imported and then introduced misbranded drug products into interstate commerce. He then laundered money gained from that illegal activity and conspired to obstruct justice by destroying documents and other objects to prevent their use in a criminal investigation.

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. Singh's offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Mr. Singh 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. Singh received the proposal and notice of opportunity for a hearing on October 21, 2024. Mr. Singh 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 Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Division of Field Enforcement Director, finds that Mr. Harpreet Singh has been convicted of multiple felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Singh 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 (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. Singh is a prohibited act.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04028 Filed 3–12–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4887]

John Warrington Kosolcharoen: 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) permanently debarring John Warrington Kosolcharoen from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application (BLA). FDA bases this order on a finding that Mr. Kosolcharoen was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Kosolcharoen was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of December 26, 2024 (30 days after receipt of the notice), Mr. Kosolcharoen has not responded. Mr. Kosolcharoen's failure to respond and request a hearing constitutes a waiver of Mr. Kosolcharoen's right to a hearing concerning this matter.

DATES: This order is applicable March 13, 2025.

ADDRESSES: Any application by Mr. Kosolcharoen for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2024–N–4887. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application.