defraud and mislead in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)). The underlying facts supporting the conviction are as follows: As contained in the Information and Plea Agreement from Mr. Cosie's case, from approximately 2016 through 2020, he owned and operated several businesses including HCGRK LLC a/k/a Health Conscious Group Rx LLC (HCGRX). According to its website, HCGRX advertised itself as a national distributor of competition quality weight loss, body building and sports supplements. The website also advertised products for the treatment of erectile dysfunction, which were described as generic versions of the prescription drugs VIAGRA (sildenafil) and CIALIS (tadalafil). Among other supplements, Mr. Cosie sold a number of products containing Human Chorionic Gonadotropin (''HCG''). HCG is a hormone produced by the placenta during pregnancy. FDA has approved several prescription drugs containing HCG for the treatment of female infertility and for other medical conditions. FDA has not approved any HCG-containing products for weight loss, nor for any purpose without a prescription. Mr. Cosie falsely claimed on his website that his company was cooperating with international pharmacies to ship orders out. In fact, Mr. Cosie obtained unapproved prescription drugs containing HCG from foreign manufacturers and other sources. Then, after importing those drugs, Mr. Cosie would apply to the vials his own counterfeit labels which he created and printed and which contained false and misleading information. Mr. Cosie then knowingly and intentionally sold the drugs to consumers without a prescription or the supervision of a licensed medical practitioner. From October 28, 2017, through December 24, 2020, Mr. Cosie received approximately $626,202.77 in proceeds from distribution of misbranded prescription drugs, and $20,000 for the sale of HCGRX.

FDA sent Mr. Cosie, by certified mail, on December 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. Cosie's felony convictions under Federal law for introducing misbranded drugs into interstate commerce with the intent to defraud and mislead in violation of sections 301(a) and 303(a)(2) of the FD&C Act, was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Cosie illegally imported and introduced misbranded prescription drug products into interstate commerce. 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. Cosie's offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Mr. Cosie 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. Cosie received the proposal and notice of opportunity for a hearing on December 7, 2024. Mr. Cosie 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 Director, Division of Enforcement, finds that Mr. Jonathan Corbett Cosie has been convicted of 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. Cosie 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 by, with the assistance of, or at the direction of Mr. Cosie is a prohibited act.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04030 Filed 3–12–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5601]

E6(R3) Good Clinical Practice: Annex 2; International Council for Harmonisation; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the draft guidance for industry entitled ''E6(R3) Good Clinical Practice: Annex 2,'' announced in the **Federal Register** of December 30, 2024. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the draft guidance published December 30, 2024 (89 FR 106519). Submit either electronic or written comments on the draft guidance by March 31, 2025, 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–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]

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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