stakeholders would like to share on this topic. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including available supporting information.

1. Should FDA focus on adding MDE information for certain excipients? If so, which excipients should be prioritized for inclusion of MDE information and why?

2. Should FDA focus on prioritizing excipients used in certain categories of drug products (*e.g.,* oral or topical products)? If so, which categories and which specific excipients used in those categories should be prioritized and why?

3. Is dosage form information in the IID helpful to your drug development program? If so, please explain how dosage form information in the IID is used in your drug development program.

4. Is the current structure or format of the IID difficult to navigate? If so, how can it be improved?

Dated: March 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–06031 Filed 3–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0415]

Irfanali Nisarali Momin: 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 Irfanali Nisarali Momin 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. Momin was convicted of one felony count under Federal law for conspiracy. The factual basis supporting Mr. Momin's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Momin 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 December 26, 2021 (30 days after receipt of the notice), Mr. Momin had not responded. Mr. Momin'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 22, 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 February 12, 2021, Mr. Momin was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the District of Georgia, Rome Division, when the court entered judgment against him for the offense of conspiracy, in violation of 18 U.S.C. 371. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the information in Mr. Momin's case, filed on September 23, 2020, to which he plead guilty, between August 2014 and November 2018, Mr. Momin along with his co-conspirators, illegally imported misbranded drugs from China that he marketed for male enhancement under names such as ''Black Ant King,'' ''Bull,'' ''Rhino 7,'' ''Super Hard,'' ''Herb Viagra,'' ''Jack Rabbit,'' ''Zhen Gongfu,'' ''Stree Overlord,'' ''Pro Power Max,'' ''A Traditional Chinese Medicine-Kidney Reinforcing Pallet,'' ''Libigrow,'' ''Red Mamba,'' ''Rhino 69,'' ''Krazzy Rhino,'' ''Rhino 25,'' Hard Steel,'' and ''Black Mamba.'' These products contained sildenafil, the active pharmaceutical ingredient in Pfizer, Inc.'s FDA-approved erectile dysfunction drug, VIAGRA, and/or tadalafil, the active pharmaceutical ingredient in Eli Lilly & Company's FDA-approved erectile dysfunction drug, CIALIS. Both VIAGRA and CIALIS can be obtained in the United States only with a prescription from a practitioner licensed by law to administer such drugs pursuant to section 503(b) of the FD&C Act (21 U.S.C. 353(b)). In order to evade U.S. import restrictions, Mr. Momin illegally imported misbranded drugs into the United States from China. As per the conspiracy Mr. Momin was involved in, the U.S. Customs declarations on the boxes containing the misbranded drugs falsely declared the contents of the boxes to be something other than misbranded drugs, such as beauty products and health products, to make it appear that the boxes contained items that could legally be imported into the United States. Mr. Momin then introduced and delivered for introduction into interstate commerce these misbranded drugs containing undeclared sildenafil and tadalafil, in violation of sections 301(a), 301(c), 303(a)(2), 502(a), and 502(f) of the FD&C Act (21 U.S.C. 331(a), 331(c), 333(a)(2), 352(a) and 352(f)).

As a result of this conviction, FDA sent Mr. Momin, by certified mail, on November 19, 2021, 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. Momin's felony conviction under Federal law for conspiracy, in violation of 18 U.S.C. 371, was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported and then introduced misbranded tadalafil and sildenafil 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. Momin's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Momin 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. Momin received the proposal and notice of opportunity for a hearing at his residence on November 26, 2021. Mr. Momin 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. Irfanali Momin has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense 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. Momin is debarred for a period of 5 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 or controlled substance by, with the assistance of, or at the direction of Mr. Momin is a prohibited act.

Any application by Mr. Momin for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0415 and sent to the Division of Dockets Management Staff (see **ADDRESSSES**). 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 *https://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: March 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–06052 Filed 3–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0417]

Shiba I. Momin: Final Debarment Order

AGENCY: Food and Drug Administration, Department of Health and Human Services (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 Shiba I. Momin 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 Ms. Momin was convicted of one felony count under Federal law for Conspiracy. The factual basis supporting Ms. Momin's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Momin was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 26, 2021 (30 days after receipt of the notice), Ms. Momin had not responded. Ms. Momin's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable March 22, 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 February 12, 2021, Ms. Momin was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the District of Georgia, Rome Division, when the court entered judgment against her for the offense of conspiracy, in violation of 18 U.S.C. 371.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows:

As contained in the Information in Ms. Momin's case, filed on September 23, 2020, to which she pleaded guilty, between August 2014 and November 2018, Ms. Momin along with her co-conspirators, illegally imported misbranded drugs from China that she marketed for male enhancement under names such as ''Black Ant King,'' ''Bull,'' ''Rhino 7,'' ''Super Hard,'' ''Herb Viagra,'' ''Jack Rabbit,'' ''Zhen Gongfu,'' ''Stree Overlord,'' ''Pro Power Max,'' ''A Traditional Chinese Medicine-Kidney Reinforcing Pallet,'' ''Libigrow,'' ''Red Mamba,'' ''Rhino 69,'' ''Krazzy Rhino,'' ''Rhino 25,'' Hard Steel,'' and ''Black Mamba.'' These products contained sildenafil, the active pharmaceutical ingredient in Pfizer, Inc.'s FDA-approved erectile dysfunction drug, VIAGRA, and/or tadalafil, the active pharmaceutical ingredient in Eli Lilly & Company's FDA-approved erectile dysfunction drug, CIALIS. Both VIAGRA and CIALIS can be obtained in the United States only with a prescription from a practitioner licensed by law to administer such drug pursuant to section 503(b) of the FD&C Act (21 U.S.C. 353(b)). In order to evade U.S. import restrictions, Ms. Momin illegally imported misbranded drugs into the United States from China. As per the conspiracy Ms. Momin was involved in, the U.S. Customs declarations on the boxes containing the misbranded drugs falsely declared the contents of the boxes to be something other than misbranded drugs, such as beauty products and health products, to make it appear that the boxes contained items that could legally be imported into the United States Ms. Momin then introduced and delivered for introduction into interstate commerce these misbranded drugs containing undeclared sildenafil and tadalafil, in violation of sections 301(a), 301(c), 303(a)(2), 502(a), and 502(f) of the FD&C Act (21 U.S.C. 331(a), 331(c), 333(a)(2), 352(a) and 352(f)).

As a result of this conviction, FDA sent Ms. Momin, by certified mail, on November 19, 2021, a notice proposing to debar her 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 Ms. Momin's felony conviction under Federal law for conspiracy, in violation of 18 U.S.C. 371, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally imported and then introduced misbranded tadalafil and sildenafil 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 Ms. Momin's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.