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.

The proposal informed Ms. Momin of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Momin received the proposal and notice of opportunity for a hearing at her residence on November 26, 2021. Ms. Momin failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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 Ms. Shiba I. 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, Ms. 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 Ms. Momin is a prohibited act.

Any application by Ms. Momin for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0417 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 *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. 2022–06036 Filed 3–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0336]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. This meeting will be held to discuss considerations for use of COVID–19 vaccine booster doses and the process for COVID–19 vaccine strain selection to address current and emerging variants. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on April 6, 2022, from 8:30 a.m. to 5 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by April 5, 2022. Comments received on or before March 31, 2022, will be provided to the committee. Comments received after March 31, 2022, and by April 5, 2022, will be taken into consideration by FDA.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtu.be/x8rq247E80I.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0336. The docket will close on April 5, 2022. Submit either electronic or written comments on this public meeting by April 5, 2022. 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 April 5, 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.

Comments received on or before March 31, 2022, will be provided to the committee. Comments received March 31, 2022, and by April 5, 2022, will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2022–N–0336 for ''Vaccines and Related Biological Products Advisory Committee (VRBPAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be