TABLE 1—FEE SCHEDULE FOR FY 2021

Fee category	FY 2021 fee rates
OMOR:	
Tier 1	$500,000
Tier 2	100,000
Facility Fees:	
MDF	20,322
CMO	13,548

VI. Fee Payment Options and Procedures

The new fee rates are for the period from October 1, 2020, through September 30, 2021. To pay the OMOR, MDF, and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: *https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp.* A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card for payments under $25,000 (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* only full payments are accepted. No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an OMOR request, for example, and other penalties. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

If you are assessed an FY 2021 OMUFA facility fee and believe your facility is not an OTC monograph drug facility as described in this notice, please contact *CDERCollections@fda.hhs.gov.*

Dated: March 23, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06361 Filed 3–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1682]

Ursula Wing: 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 Ursula Wing 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. Wing was convicted of one felony count under Federal law for conspiracy to defraud the United States. Ms. Wing was given notice of the proposed debarment and an opportunity to request a hearing to show why she should not be debarred within the timeframe prescribed by regulation. Ms. Wing failed to request a hearing. Ms. Wing'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 26, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), 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 July 10, 2020, Ms. Wing was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Western District of Wisconsin, when the court accepted her plea of guilty and entered judgment against her for the felony offense of conspiracy to defraud the United States in violation of 18 U.S.C. 371.

FDA's finding that debarment is appropriate is based on this felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in count 1 of the indictment in Ms. Wing's case, filed on June 26, 2019, to which she pleaded guilty, from in or about June 2016 and continuing to on or about June 21, 2018, she operated a blog under the name ''the Macrobiotic Stoner'' and a fake jewelry business under the name ''Morocco International Inc.'' Ms. Wing used both entities to sell unapproved and misbranded prescription drugs to consumers in the United States and around the world and to process payments for those drugs. Throughout the course of this conspiracy Ms. Wing did not possess a valid wholesale drug distribution license, pharmacy license, or a license to prescribe prescription drugs. She was also not registered under section 510 of the FD&C Act (21 U.S.C. 360) as a person who owns or operates an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug.

As part of this conspiracy, Ms. Wing imported foreign-sourced prescription drugs in wholesale quantities from India into the United States. The imported drugs contained U.S. Customs Declaration Forms falsely stating that the contents were ''personal supply medication'' and did not contain any dangerous articles or articles prohibited by postal or customs regulations. The drugs Ms. Wing imported were foreign versions of mifepristone and misoprostol. There are two 200 mg mifepristone tablets that are FDA-

approved for use in a regimen with misoprostol for the medical termination of early pregnancy. There are no approved drug applications pursuant to section 505 of the FD&C Act (21 U.S.C. 355) in effect for the mifepristone and misoprostol Ms. Wing imported and sold via her website. In addition to being unapproved, the drugs sold via Ms. Wing's website were also misbranded because they failed to bear adequate directions for their intended use (see 21 U.S.C. 352(f)(1) and 21 CFR 201.5) and are prescription medications that were dispensed without a prescription from a practitioner licensed by law to administer such drugs (21 U.S.C. 353(b)(1) and 331(k)).

Ms. Wing broke down the bulk shipments of unapproved and misbranded drugs she received from India and repackaged them into retail quantities which she then shipped to customers in the United States and around the world via U.S. mail. To disguise her sales, Ms. Wing created a fake company called ''Fatima's Bread Basket,'' which she listed as the shipper on the envelope going to the customer. Ms. Wing then inserted a piece of jewelry in the shipping envelope to serve as the cover piece of merchandise being mailed to the customer. She packaged the unapproved and misbranded prescription drugs in a smaller packet that was in a hidden panel and taped to the inside of the shipping envelope. Ms. Wing disguised the nature of the item being purchased by listing on the invoice alternate jewelry product names, each of which had a code to indicate the actual item (unapproved and misbranded drug(s)) being ordered.

As a result of this conviction, FDA sent Ms. Wing, by certified mail on October 15, 2020, 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. Wing's conviction for one felony count under Federal law, for conspiracy to defraud the United States, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally smuggled unapproved and misbranded prescription drugs from India into the United States and then distributed those misbranded and unapproved drugs to consumers both in the United States and abroad.

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. Wing's offense, and concluded that this felony offense warranted the imposition of a 5-year period of debarment. The proposal informed Ms. Wing 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. Wing received the proposal and notice of opportunity for a hearing on October 19, 2020. Ms. Wing 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. Ursula Wing 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. Wing 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. Wing is a prohibited act.

Any application by Ms. Wing for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–1682 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 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06258 Filed 3–25–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0273]

Arthritis 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 Arthritis Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will take place virtually on May 6, 2021, from 10 a.m. to 4:15 p.m. Eastern Time.

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. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0273. The docket will close May 5, 2021. Submit either electronic or written comments on this public meeting by May 5, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 5, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 5, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before April 22, 2021, will be provided to the committee. Comments received after that date 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.