a hearing on December 14, 2020. Mr. Whalen 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. Whalen 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. Whalen 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 or controlled substance by, with the assistance of, or at the direction of Mr. Whalen is a prohibited act.

Any application by Mr. Whalen for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–2002 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. 2021–06219 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–2246]

Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates under the Over-the-Counter (OTC) Monograph Drug user fee program for fiscal year (FY) 2021. On March 27, 2020, new provisions were added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which authorize FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests. FDA refers to the OTC Monograph Drug user fee program as ''OMUFA'' throughout this document. This notice publishes the OMUFA fee rates for FY 2021.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–9845.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j-72), as added by the CARES Act, authorizes FDA to assess and collect: (1) Facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests. These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act and include various FDA activities associated with OTC monograph drugs and inspection of facilities associated with such products. For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act);
- An OTC monograph drug facility (MDF) is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act);
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act); and
- An OTC Monograph Order Request (OMOR) is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2021 shall be assessed with respect to each facility that is identified as an OTC monograph drug facility during the period from January 2020 through December 2020. Consistent with the statute, FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees are due 45 days after the date of publication of this notice (see section 744M(a)(1)(D)(i) of the FD&C Act).[1]

As discussed in greater detail below:

- OTC monograph drug facilities are exempt from FY 2021 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to December 31, 2019 (see section 744M(a)(1)(B)(i) of the FD&C Act).
- Entities that registered with FDA during the Coronavirus Disease 2019 (COVID–19) pandemic whose sole activity with respect to OTC monograph drugs during the pandemic consists (or had consisted) of manufacturing OTC hand sanitizer products are not identified as OTC monograph drug facilities subject to OMUFA facility fees.[2]

In addition to facility fees, the Agency is authorized to assess and collect fees from submitters of OMORs, except for OMORs which request certain safety-related changes (as discussed below).

[1] FDA is required to publish OMUFA fee rates under section 744M(a)(4) of the FD&C Act. FDA published an earlier version of this notice in the **Federal Register** on December 29, 2020. That notice was withdrawn by the Department of Health and Human Services (HHS) on January 6, 2021 (see *https://www.federalregister.gov/documents/2021/01/06/2021-00030/withdrawal-of-fda-notice-regarding-fee-rates-under-the-over-the-counter-monograph-drug-user-fee*). FDA has updated and is republishing the OMUFA fee rates for FY 2021 consistent with the January 12, 2021, HHS notice described below (and with the concurrence of HHS that publication of this fee-setting notice does not require prior notice and comment).

[2] See HHS **Federal Register** notice of January 12, 2021, *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during.*

There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.[3]

For FY 2021, the OMUFA fee rates are as follows: Tier 1 OMOR fees ($500,000), Tier 2 OMOR fees ($100,000), MDF facility fees ($20,322), and CMO facility fees ($13,548). These fees are for the period from October 1, 2020, through September 30, 2021.[4] This document is issued pursuant to sections 744M(a)(4) and (c)(4)(A)[5] of the FD&C Act and describes the calculations used to set the OMUFA facility fees and OMOR fees for FY 2021 in accordance with the directives in the statute.

II. Facility Fee Revenue Amount for FY 2021

A. Base Fee Revenue Amount

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year established by section 744M(b) of the FD&C Act. The yearly base revenue amount is the starting point for setting annual facility fee rates. The base revenue amount for FY 2021 is $8,000,000 (see section 744M(b)(3)(A) of the FD&C Act).

B. Fee Revenue Adjustment for Inflation

Under OMUFA, the annual base revenue amount for facility fees is adjusted for inflation for FY 2022 and each subsequent FY (see section 744M(c)(1) of the FD&C Act). Because the adjustment for inflation does not apply until FY 2022, the FY 2021 facility fee revenue is not subject to an inflation adjustment by FDA.

C. Fee Revenue Adjustment for Additional Direct Cost

Under OMUFA, $14,000,000 is added to the facility fee revenues for FY 2021 to account for additional direct costs (see section 744M(c)(3)(A) of the FD&C Act).

D. Fee Revenue Adjustment for Operating Reserve

Under OMUFA, FDA may further increase the FY 2021 facility fee revenue and fees if such an adjustment is necessary in order to provide up to 3 weeks of operating reserves of carryover user fees for OTC monograph drug activities (see section 744M(c)(2)(A) of the FD&C Act). However, under the statute, if the carryover balance exceeds 10 weeks of operating reserves, FDA is required to decrease fees to provide for not more than 10 weeks of operating reserves of carryover user fees (see section 744M(c)(2)(C) of the FD&C Act).

FDA is applying the operating reserve adjustment to increase the FY 2021 facility fee revenue and fees to enable the Agency to maintain 3 weeks of operating reserves of carryover user fees. To determine the 3-week operating reserve amount, the FY 2021 annual base revenue adjusted for additional direct costs (*i.e.,* $8,000,000 + $14,000,000 = $22,000,000), is divided by 52, and then multiplied by 3. The 3-week operating reserve amount for FY 2021 is $1,269,231.

As a result of the above calculations, the final FY 2021 OMUFA target facility fee revenue is $23,269,000 (rounded to the nearest thousand dollars).

III. Determination of FY 2021 OMOR Fees

Under OMUFA, the FY 2021 Tier 1 OMOR fee is $500,000 and the Tier 2 OMOR fee is $100,000 (see section 744M(a)(2)(A)(i) and (ii) of the FD&C Act, respectively). OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b)(1) of the FD&C Act).

An OMOR fee is generally assessed to each person who submits an OMOR (see section 744M(a)(2)(A) of the FD&C Act). OMOR fees are due on the date of the submission of the OMOR (see section 744M(a)(2)(B) of the FD&C Act). The payor should submit the OMOR fee that applies to the type of OMOR they are submitting (*i.e.,* Tier 1 or Tier 2). FDA will determine whether the requestor has submitted the appropriate OMOR fee following receipt of the OMOR and the fee.

An OMOR fee will not be assessed if the OMOR seeks to make certain safety changes with respect to an OTC monograph drug. Specifically, no fee will be assessed if FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) A contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug (see section 744M(a)(2)(C) of the FD&C Act).

IV. Facility Fee Calculations

A. Facility Fee Revenues and Fees

For FY 2021, facility fee rates are being established to generate a total target revenue amount, as determined under the statute, equal to $23,269,000 (rounded to the nearest thousand dollars). FDA used the methodology described below to determine the appropriate number of MDF and CMO facilities to be used in setting the OMUFA facility fees for FY 2021. FDA took into consideration that the CMO facility fee is equal to two-thirds of the amount of the MDF facility fee (see section 744M(a)(1)(B)(ii) of the FD&C Act).

B. Calculating the Number of Qualifying Facilities and Setting the Facility Fees

Under the statute, certain information submitted to FDA for drug establishment registration purposes under section 510 of the FD&C Act is also used for OMUFA fee-setting (see section 744M(d) of the FD&C Act). Thus, for FY 2021, FDA utilized the Agency's Electronic Drug Registration and Listing System (eDRLS) to calculate the number of qualifying MDF or CMO facilities that engage in the manufacturing or processing of the finished dosage form of an OTC monograph drug. In order to apply the statutory fee-setting calculations, FDA assessed which OTC monograph drug facilities had selected in eDRLS the business operation qualifiers of ''manufactures human over-the-counter drug products produced under a monograph'' or ''contract manufacturing for human over-the-counter drug products produced under a monograph'' and indicated at least one of the following business operations: finished dosage form manufacture, label, manufacture, pack, relabel, or repack.[6] FDA analyzed eDRLS

[3] Under OMUFA, a Tier 1 OMOR is defined as any OMOR which is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.

[4] These OMUFA fees are for FY 2021, per section 744M(a) of the FD&C Act.

[5] Although under section 744M(c)(4)(A) of the FD&C Act, FDA was to publish this notice not later than the second Monday in May 2020, we note that under section 744M(f)(1) of the FD&C Act, OMUFA fees ''shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.'' An appropriation of FY 2021 OMUFA fees was provided under section 123 of the Continuing Appropriations Act, 2021, Division A of Public Law 116–159 (October 1, 2020). Additionally, as described above, this notice republishes the FY 2021 OMUFA fees following withdrawal of the Agency's earlier December 29, 2020, fee notice.

[6] *See* section 744L(10)(A); see also section 744L(10)(A)(iii) of the FD&C Act, excluding from the definition of ''OTC monograph drug facility'' those facilities whose manufacturing or processing consists solely of a narrow range of specified activities (*e.g.,* placement of outer overpackaging on products already in final packaged form); *cf* section 744A(6)(A)(ii) of the FD&C Act. *See also* 21 CFR 207.1 (addressing drug establishment registration), stating that ''[m]anufacture means each step in the manufacture, preparation, propagation, compounding, or processing of a drug,'' and indicating that ''the term 'manufacture, preparation, propagation, compounding, or processing,' as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes relabeling, repackaging, and salvaging activities.''

registration data from January 1, 2020, through December 31, 2020,[7] based on information provided by facilities in eDRLS.

Those facilities that only manufacture the Active Pharmaceutical Ingredient (API) of an OTC monograph drug do not meet the definition of an OTC monograph drug facility (see section 744L(10)(A)(i)(II)) of the FD&C Act). Likewise, a facility is not an OTC monograph drug facility if its only manufacturing or processing activities are one or more of the following: (1) Production of clinical research supplies; (2) testing; or (3) placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging (see section 744L(10)(A)(iii) of the FD&C Act).

Further, in a January 12, 2021, **Federal Register** notice, the Department of Health and Human Services (HHS) clarified that ''persons that entered into the over-the-counter drug industry for the first time in order to supply hand sanitizers during the COVID–19 Public Health Emergency are not persons subject to the facility fee the Secretary is authorized to collect'' under section 744M of the FD&C Act.[8] As the January 12, 2021, HHS notice explained, persons that were not registered with FDA as drug manufacturers prior to the COVID–19 Public Health Emergency, which then later registered with FDA for the purpose of producing hand sanitizers, ''are not 'identified . . .facilit[ies]' under section 744M of the FD&C Act, 21 U.S.C. 379j-72, and are thus not subject to the facility fee contained therein'' (86 FR 2421). As further explained in the HHS notice, ''imposing facility fees on these entities is inconsistent with Congress' stated intent elsewhere in the CARES Act.'' Section 2308 of the CARES Act provides a temporary exemption from excise taxes for distilled spirits ''use[d] in or contained in hand sanitizer produced and distributed in a manner consistent with any guidance issued by the Food and Drug Administration that is related to the outbreak of [COVID–19].'' As stated in the HHS notice, ''[i]t is unlikely Congress intended to save these entities from excise taxes only to impose tens of thousands of dollars in facility fees from an unfamiliar regulator.'' (86 FR 2420 at 2421)

Accordingly, as stated in the January 12, 2021, HHS Notice, FDA will not assess OMUFA facility fees upon those firms that first registered with FDA on or after the January 27, 2020 declaration of the COVID–19 Public Health Emergency (PHE),[9] *solely* for purposes of manufacturing hand sanitizer products[10] during the PHE.[11] We note, however, that under the FD&C Act, whether an entity is subject to OMUFA fees has no bearing on whether the entity or the entity's products are subject to other requirements under the FD&C Act. FDA will continue to use its regulatory compliance and enforcement tools to protect consumers, including from potentially dangerous or subpotent hand sanitizers.

In addition, FDA will not assess a facility fee if the identified OTC monograph drug facility: (1) Has ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year and (2) has updated its eDRLS registration to reflect that change (per section 744M(a)(1)(B)(i) of the FD&C Act). As the applicable fiscal year for fee-setting under this notice is FY 2021, the year immediately preceding the applicable fiscal year is FY 2020. December 31 of FY 2020 is December 31, 2019. Thus, FDA will not assess a FY 2021 facility fee with respect to an OTC monograph drug facility that, prior to December 31, 2019, had ceased all activities related to OTC monograph drugs and updated its eDRLS registration to that effect.

FDA considered a number of factors that could affect collection of the target revenue, including that FY 2021 is the first year of this new user fee program and uncertainties related to the effects of the COVID–19 PHE. In undertaking the statutorily-directed fee calculations, the Agency made certain assumptions, including that: (1) Facilities using expired business operation qualifier codes within their electronic registration (also known as Structured Product Labeling) codes in eDRLS were no longer manufacturing and marketing OTC monograph drugs; (2) facilities that have deregistered in eDRLS have exited the market; (3) facilities that FDA believes registered incorrectly as OTC monograph drug facilities (for example, because the associated drug listings for these facilities did not include OTC monograph drugs but instead indicated such products as OTC drug products under an approved drug application or OTC animal drug products) were not engaged in manufacturing or processing the finished dosage form of an OTC monograph drug; and (4) facilities that registered but did not have an active OTC monograph drug product listing associated in their registration profile were not manufacturing or processing such drug products.

Each establishment paying the facility fee is counted as one fee-paying unit. The total estimate of fee-paying units is further analyzed to determine the number of respective MDF and CMO fee-paying units.

Based on the data obtained from eDRLS, FDA estimates there will be 1,184 fee-paying units. The Agency estimates that 90 percent ($1{,}184 \times .90 = 1{,}066$, rounded) will incur the MDF fee and 10 percent ($1{,}184 \times .10 = 118$, rounded) will incur the CMO fee.

To determine the number of full fee-paying equivalents (the denominator) to be used in setting the OMUFA fees, FDA assigns a value of 1 to each MDF (1,066) and a value of ⅔ to each CMO ($118 \times ⅔ = 79$) for a full facility equivalent of 1,145 (rounded). The target fee revenue of $23,269,000 is then divided by 1,145 for an MDF fee of $20,322 and a CMO fee of $13,548.

V. Fee Schedule for FY 2021

The fee rates for FY 2021 are displayed in table 1.

[7] Under section 744M(a)(1) of the FD&C Act, ''Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility.'' For purposes of FY 2021 facility fees, that time period is January 1, 2020, through December 31, 2020.

[8] See *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during* (86 FR 2420).

[9] See *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[10] The term ''hand sanitizer'' commonly refers to consumer antiseptic rubs. However, because the HHS notice referred to ''persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID–19 Public Health Emergency'' (86 FR 2420), we are using the same terminology—''hand sanitizer products''—to refer to OTC monograph drug products intended for use (without water) as antiseptic hand rubs or antiseptic hand wipes by consumers or health care personnel, including products manufactured or prepared consistent with the Agency's ''Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19) Guidance for Industry'' (see *https://www.fda.gov/media/136289/download*). Our use of the term ''hand sanitizer products'' in this notice to refer to antiseptic hand rubs and antiseptic hand wipes intended for use by consumers or health care personnel does not alter any existing regulatory distinctions between these products.

[11] *See* 86 FR 2420. The January 12, 2021, HHS notice explained that fees would be assessed on entities that ''manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer'' and entities that ''continue to manufacture (as opposed to hold, distribute, or sell existing inventories) hand sanitizer products as of December 31 of the year immediately following the year during which the COVID–19 Public Health Emergency is terminated.''

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-