TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910–0119	02/29/2024
Orphan Drugs	0910–0167	02/29/2024
Electronic Records: Electronic Signatures	0910–0303	02/29/2024
Extra Label Drug Use in Animals	0910–0325	02/29/2024
Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured from, Processed With, or Otherwise Containing, Material from Cattle	0910–0623	02/29/2024
Application for Participation in Food and Drug Administration Fellowship Programs	0910–0780	02/29/2024
Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion	0910–0894	02/29/2024

Dated: March 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06266 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–2002]

Thomas J. Whalen: 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 Thomas J. Whalen 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 that Mr. Whalen was convicted of multiple offenses; two of these are relevant to this debarment: One count of importation contrary of law-aiding and abetting and one count of healthcare fraud-aiding and abetting. The factual basis supporting Mr. Whalen's conviction is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Whalen 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 January 13, 2021 (30 days after receipt of the notice), Mr. Whalen had not responded. Mr. Whalen'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 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 September 15, 2020, Mr. Whalen was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Pennsylvania, when the court entered judgment against him for multiple offenses, two of which are relevant to this debarment: One count of importation contrary to law-aiding and abetting in violation of 18 U.S.C. 545 and 2, and one count of healthcare fraud-aiding and abetting in violation of 18 U.S.C. 1347 and 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for this conviction is as follows: As contained in the information in Mr. Whalen's case, filed on October 25, 2019, to which he pleaded guilty, he was a doctor of osteopathy in the Commonwealth of Pennsylvania and the State of Delaware. From about January 2014 to about March 2018, Mr. Whalen engaged in a scheme to defraud Medicare, the U.S. Office of Personnel Management (OPM), and the Independence Blue Cross insurance company (IBC). Specifically, he purchased, imported into the United States, and distributed misbranded and non-FDA-approved injectable versions of REMICADE (infliximab), SYNVISC/SYNVISC ONE (hyaluronan), ORENCIA (abatacept), PROLIA/XGEVA (denosumab), and BONIVA (ibandronate sodium). He then injected his patients with these non-FDA-approved versions of these medications. Mr. Whalen billed Medicare, OPM, and IBC for the provision of the FDA-approved versions of these products.

As a result of this conviction, FDA sent Mr. Whalen, by United Parcel Service, on December 11, 2020, 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. Whalen's felony conviction for two felony counts under Federal law related to this debarment, specifically for one count of importation contrary to law-aiding and abetting and one count of healthcare fraud-aiding and abetting, was for conduct relating to the importation into the United States of any drug or controlled substance, because he illegally imported unapproved and misbranded drugs into the United States and then distributed those misbranded and unapproved drugs to consumers in the United States.

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. Whalen's offenses and concluded that each felony offense warranted the imposition of a 5-year period of debarment, for a total debarment period of 10 years. The proposal informed Mr. Whalen 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. Whalen received the proposal and notice of opportunity for

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.*