accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16062 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2366]

Justin Ash: Final Debarment Order

AGENCY: Food and Drug Administration, 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 Justin Ash 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. Ash was convicted of one felony count under Federal law for conspiracy to commit offenses against the United States. The factual basis supporting Mr. Ash's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Ash 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 April 4, 2021 (30 days after receipt of the notice), Mr. Ash had not responded. Mr. Ash'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 July 28, 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 (ELEM–4029), 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 November 24, 2020, Mr. Ash was convicted, as defined in section 306(l)(1) of FD&C Act, in the U. S. District Court for the Western District of Pennsylvania, when the court entered judgment against him for the offense of conspiracy to commit offenses against the United States, 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. Ash's case, filed December 10, 2019, to which he plead guilty, from on or about January 1, 2016, and continuing until May 8, 2018, he controlled an internet-based business entity known as both DRC and Domestic RCS (hereinafter DRC). During this time, Mr. Ash obtained bulk supplies of clonazolam, diclazepam, flubromazolam, and etizolam (none of which have been approved for use by FDA in the United States) from overseas sources, including from suppliers in China. Mr. Ash caused his overseas suppliers to ship these drugs in smaller quantities to multiple addresses in the United States he controlled to draw less government scrutiny. After receiving these bulk drugs, Mr. Ash caused his employees to press them into pills and package them. Mr. Ash caused the pill packaging to include disclaimers stating that the drugs were for research purposes only, in part to evade detection by regulatory authorities, including FDA. Mr. Ash then had the packages shipped to customers throughout the United States who ordered the drugs through a website he operated.

As a result of this conviction, FDA sent Mr. Ash, by certified mail, on February 26, 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. Ash's felony conviction under Federal law for conspiracy to commit offenses against the United States, 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, manufactured, repackaged, and then introduced unapproved clonazolam, diclazepam, flubromazolam, and etizolam drug products 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. Ash's offense, and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Ash 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. Ash received the proposal and notice of opportunity for a hearing on March 5, 2021. Mr. Ash 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. Justin Ash 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. Ash 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. Ash is a prohibited act.

Any application by Mr. Ash for termination of debarment under section 306(d)(1) of the FD&C Act should be

identified with Docket No. FDA–2020–N–2366 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: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16044 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0704]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2022

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2022 annual fee rate for importers approved to participate in the Voluntary Qualified Importer Program (VQIP) that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). This fee is effective August 1, 2021, and will remain in effect through September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Donald Prater, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3202, Silver Spring, MD 20993, 301–348–3007.

SUPPLEMENTARY INFORMATION:

I. Background

Section 302 of FSMA, Voluntary Qualified Importer Program, amended the FD&C Act to create a new provision, section 806, under the same name. Section 806 of the FD&C Act (21 U.S.C. 384b) directs FDA to establish a program to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program, and a process, consistent with section 808 of the FD&C Act (21 U.S.C. 384d), for the issuance of a facility certification to accompany a food offered for importation by importers participating in the VQIP.

Section 743 of the FD&C Act (21 U.S.C. 379j–31) authorizes FDA to assess and collect fees from each importer participating in VQIP to cover FDA's costs of administering the program. Each fiscal year, fees are to be established based on an estimate of 100 percent of the costs for the year. The fee rates must be published in a **Federal Register** notice not later than 60 days before the start of each fiscal year (section 743(b)(1) of the FD&C Act). After FDA approves a VQIP application, the user fee must be paid before October 1, the start of the VQIP fiscal year, to begin receiving benefits for that VQIP fiscal year.

The FY 2022 VQIP user fee will support benefits from October 1, 2021, through September 30, 2022.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2022

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2022. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2022

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2022 cost. The FY 2022 FDA-wide average cost for payroll (salaries and benefits) is $171,228; non-payroll—including equipment, supplies, IT, general and administrative overhead—is $101,625; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $23,597 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2022 average fully supported cost to $296,450 per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2022 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2022 average fully supported cost of $296,450 per FTE by the average number of supported direct FDA work hours in FY 2020—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2020

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	−80
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
23 days of general administration	−184
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2022 ($296,450) by the total number of supported direct work hours available for assignment in FY 2020 (1,160) results in an average fully supported cost of $256 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2022.

B. Adjusting FY 2020 Travel Costs for Inflation To Estimate FY 2022 Travel Costs

To adjust the hourly rate for FY 2022, FDA must estimate the cost of inflation in each year for FY 2021 and FY 2022. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1)), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2021 inflation rate to be 1.3493 percent; this rate was published in the FY 2021 PDUFA user fee rates notice in the **Federal Register** (August 3, 2020, 85 FR 46651). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.3493 percent for FY