

FOR FURTHER INFORMATION CONTACT:

Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993-0002, 301-796-2398 and/or PSG-Questions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a draft guidance on a generic olodaterol hydrochloride; tiotropium bromide inhalation spray.

FDA initially approved new drug application (NDA) 206756 for STIOLTO RESPIMAT (olodaterol hydrochloride; tiotropium bromide inhalation spray) in May 2015. We are now issuing draft guidance for industry on BE recommendations for generic olodaterol hydrochloride; tiotropium bromide inhalation spray (“Draft Guidance for Olodaterol Hydrochloride; Tiotropium Bromide”).

In October 2012, Boehringer Ingelheim, manufacturer of the reference listed drug SPIRIVA HANDIHALER, NDA 21395, submitted a citizen petition requesting, among other things, that FDA adopt and apply certain requirements in its review of any proposed generic and follow-on versions of SPIRIVA HANDIHALER or any other Boehringer Ingelheim oral inhalation product containing the active ingredient tiotropium bromide under section 505(j) and (b)(2), respectively, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j) and (b)(2)) (Docket No. FDA-2012-P-1072). Boehringer Ingelheim submitted a supplement to the citizen petition in January 2021 further expanding on its initial petition requests. FDA is reviewing the issues raised in the petition and supplement and will consider any comments on the draft guidance entitled “Draft Guidance for Olodaterol Hydrochloride; Tiotropium Bromide” before responding to Boehringer’s citizen petition.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the information and data to demonstrate BE to support ANDAs for tiotropium bromide inhalation spray. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2021-N-0702]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2022 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that

are applying to be directly accredited by FDA.

DATES: This fee is effective October 1, 2021.

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 307 of FSMA (Pub. L. 111-353), Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies¹ conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled “Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program” (81 FR 90186, December 14, 2016).

The FSMA FY 2022 third-party certification program user fee rate announced in this notice is effective on October 1, 2021 and will remain in effect through September 30, 2022.

¹ For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578-74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term “third-party certification body” rather than the term “third-party auditor” used in section 808(a)(3) of the FD&C Act.

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

FDA must estimate 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 the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, 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, information technology, 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 third-party certification user fees for FY 2022 prior to including 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
26.5 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 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 2021 and 2.2013 percent for FY 2022, and FDA intends to use this inflation rate to make inflation adjustments for FY 2022; the derivation of this rate will be published in the **Federal Register** in the FY 2022 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2021 and 2022, therefore, is 1.035803 (or 3.5803 percent) (calculated as 1 plus 1.35803 percent times 1 plus 2.2013 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of \$256 already takes into account inflation as the calculation above is based on FY 2022 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program

fees for FY 2022 prior to including travel costs as applicable for the activity. For the purpose of estimating the fee, we are using the travel cost rate for foreign travel because we anticipate that the vast majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2020, the Office of Regulatory Affairs spent a total of \$1,449,058 on 171 foreign inspection trips related to FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine field activities programs, which averaged a total of \$8,474 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing \$8,474 per trip by 120 hours per trip results in a total and an additional cost of \$71 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2020. To adjust \$71 for inflationary increases in FY 2021 and FY 2022, FDA must multiply it by the same inflation factor mentioned previously in this document (1.035803 or 3.5803 percent), which results in an estimated cost of \$74 (rounded to the nearest dollar) per paid hour in addition to \$256 for a total of \$330 per paid hour (\$256 plus \$74) for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2022 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2022

Fee category	Fee rates for FY 2022
Hourly rate without travel	\$256
Hourly rate if travel is required	330

III. Fees for Accreditation Bodies and Certification Bodies in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

The third-party certification program assesses application fees and annual fees. In FY 2022, the only fees that could be collected by FDA under section 808(c)(8) of the FD&C Act are the initial application fee for accreditation bodies seeking recognition, the annual fee for recognized accreditation bodies, the annual fee for certification bodies accredited by a recognized accreditation body, the initial application fee for a certification body seeking direct accreditation from FDA, and the renewal fee for recognized accreditation bodies. Table 3 provides an overview of the fees for FY 2022.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2022

Fee category	Fee rates for FY 2022
Initial Application Fee for Accreditation Body Seeking Recognition	\$44,512
Annual Fee for Recognized Accreditation Body	2,064
Annual Fee for Accredited Certification Body	2,580
Initial Application Fee for a Certification Body Seeking Direct Accreditation From FDA	44,512
Renewal Application Fee for Recognized Accreditation Body	27,120

A. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(1) (21 CFR 1.705(a)(1)) establishes an application fee for accreditation bodies applying for initial recognition that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will continue to reconsider the estimated hours. Based on data we have acquired since starting the program, we estimate that it would take, on average, 80 person-hours to review an accreditation body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, \$256/hour, to calculate the portion of the user fee attributable to those activities: $\$256/\text{hour} \times (80 \text{ hours (application review)} + 32 \text{ hours (written report)}) = \$28,672$. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, \$330/hour, to calculate

the portion of the user fee attributable to those activities: $\$330/\text{hour} \times 48 \text{ hours (i.e., two fully supported FTEs} \times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))) = \$15,840$. The estimated average cost of the work FDA performs in total for reviewing an initial application for recognition for an accreditation body based on these figures would be $\$28,672 + \$15,840 = \$44,512$. Therefore, the application fee for accreditation bodies applying for recognition in FY 2022 will be \$44,512.

B. Annual Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for each recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. At this time, we assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. As the program proceeds, we will adjust the term of recognition as appropriate. We estimate that for one performance evaluation of a recognized accreditation body, it would take, on average (taking into account that not all recognized accreditation bodies would be monitored onsite), 22 hours for FDA to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 8 hours of onsite performance evaluation. Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single recognized accreditation body would be $\$7,680 (\$256/\text{hour} \times (22 \text{ hours (records review)} + 8 \text{ hours (written report)})) + \$2,640 (\$330/\text{hour} \times 8 \text{ hours (onsite evaluation)})$, which is \$10,320. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of \$2,064 for FY 2022.

C. Annual Fee for Certification Bodies Accredited by a Recognized Accreditation Body in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for a certification body accredited by a recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. At this time, we assume

an average term of accreditation of 4 years. This fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. We estimate that FDA would conduct, on average, the same activities, for the same amount of time to monitor certification bodies accredited by a recognized accreditation body as we would to monitor an accreditation body recognized by FDA. Using the fully supported FTE hourly rates in Table 2, the estimated average cost of the work FDA performs to monitor performance of a single accredited certification body would be $\$7,680 (\$256/\text{hour} \times (22 \text{ hours (records review)} + 8 \text{ hours (written report)})) + \$2,640 (\$330/\text{hour} \times 8 \text{ hours (onsite evaluation)})$, which is \$10,320. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of \$2,580 for FY 2022.

D. Initial Application Fee for Certification Bodies Seeking Direct Accreditation From FDA in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(3) establishes an application fee for certification bodies applying for direct accreditation from FDA that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for direct accreditation of certification bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 80 person-hours to review a certification body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, \$256/hour, to calculate the portion of the user fee attributable to those activities: $\$256/\text{hour} \times (80 \text{ hours (application review)} + 32 \text{ hours (written report)}) = \$28,672$. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For

this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, \$330/hour, to calculate the portion of the user fee attributable to those activities: $\$330/\text{hour} \times 48 \text{ hours}$ (i.e., two fully supported FTEs $\times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))$) = \$15,840. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be $\$28,672 + \$15,840 = \$44,512$. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2022 will be \$44,512.

E. Renewal Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(2) establishes a renewal application fee for recognized accreditation bodies that represents the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 43 person-hours to review an accreditation body's submitted renewal application, 24 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review renewal applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, \$256/hour, to calculate the portion of the user fee attributable to those activities: $\$256/\text{hour} \times (43 \text{ hours (application review)} + 32 \text{ hours (written report)}) = \$19,200$. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, \$330/hour, to calculate the portion of the user fee attributable to those activities: $\$330/\text{hour} \times 24 \text{ hours}$ (i.e., fully supported FTE $\times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))$) = \$7,920. The estimated average cost of

the work FDA performs in total for reviewing a renewal application for recognition of an accreditation body based on these figures would be $\$19,200 + \$7,920 = \$27,120$. Therefore, the renewal application fee for recognized accreditation bodies in FY 2022 will be \$27,120.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2022

Section 1.705(a) also establishes application fees for certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2022, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2022 based on the fully supported FTE hourly rates for FY 2022 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 4 provides an overview of the estimated fees for other fee categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2022
Renewal application fee for directly accredited certification body	\$27,120
Annual fee for certification body directly accredited by FDA	21,392

V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application. For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the receipt invoice date. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). 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 you have found your invoice, select "Pay Now" to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available only for balances 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. When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment including the invoice number on the check stub to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: this address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314-418-4013. This phone number is only for questions about courier delivery.) The tax identification number of FDA is 53-0196965. (Note: invoice copies do not need to be submitted to FDA with the payments.)

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized

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.

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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) debaring 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 clonazepam, diclazepam, flubromazepam, 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 clonazepam, diclazepam, flubromazepam, 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