Charlene Parks at (410)-786–8684 or *Charlene.Parks@cms.hhs.gov*).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2113]

Taylor McLaren: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Taylor McLaren 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. McLaren was convicted of one felony count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. McLaren's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. McLaren 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 8, 2024 (30 days after receipt of the notice), Mr. McLaren had not responded. Mr. McLaren'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 February 23, 2024.

ADDRESSES: Any application by Mr. McLaren for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–2113. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743 or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act 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 March 2, 2023, Mr. McLaren was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for Western District of Michigan when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545.

The underlying facts supporting the conviction are as follows: As contained in the indictment and plea agreement from his case, filed on March 1, 2022, and August 22, 2022, respectively, Brendon Gagne owned and operated *www.ExpressPCT.com*, which sold misbranded prescription drugs, obtained from overseas suppliers, and sold to customers in the United States without requiring a prescription. Mr. McLaren was recruited by Brendon Gagne to receive, repackage, and reship prescription drugs Mr. McLaren received from co-conspirators outside of the United States that were purchased by customers on the website *www.ExpressPCT.com.* In Mr. McLaren's plea agreement, he acknowledged he knew that receiving and reshipping prescription drugs in this manner was illegal. Later on, Mr. McLaren recruited at least one other person to be involved in the scheme by

also receiving misbranded prescription drugs from overseas suppliers.

As a result of this conviction, FDA sent Mr. McLaren, by certified mail, on November 30, 2023, 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. McLaren's felony conviction under Federal law for conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545, was for conduct relating to the importation into the United States of any drug or controlled substance because he was involved in a scheme to illegally import and introduce prescription drugs into 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. McLaren's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. McLaren 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. McLaren received the proposal and notice of opportunity for a hearing on December 9, 2023. Mr. McLaren 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. Taylor McLaren 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. McLaren 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 by, with the assistance of, or at the direction of Mr. McLaren is a prohibited act.

Dated: February 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03650 Filed 2–22–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation OMB No. 0906–0034—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. The initial notice was published on November 17, 2023, with a 60-day comment period. No comments were received. OMB will accept comments from the public during the 30-day comment period for this notice. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than March 25, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906–0034—Extension.

Abstract: The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency within HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations (42 U.S.C. 273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. 273b). The Organ Procurement and Transplantation Network final rule, 42 CFR part 121.11(b)(2), requires organ procurement organizations and transplant hospitals, ''as specified from time to time by the Secretary,'' to submit to the SRTR, as appropriate, information regarding ''donors of organs'' and ''other information that the Secretary deems appropriate.''

In 2018, a pilot living donor registry was implemented by the SRTR, and each participating transplant program registered all potential candidates for living donation who provided informed consent to enroll. In 2019, an updated version of the data collection instrument was approved, followed by the latest data collection forms which were approved on February 26, 2021. These data collection modifications were intended to improve the quality of the data and reduce the administrative burden for respondents. This **Federal Register** notice requests an extension of the last approved data collection forms (February 2021) with no changes to the total estimated annualized burden hours.

A 60-day notice published in the **Federal Register** on November 17, 2023, vol. 88, No. 221; pp. 80318–19. There were no public comments.

Need and Proposed Use of the Information: The transplant programs submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the SRTR contractor. The SRTR contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. The data collection includes outcomes of evaluation, including reasons for non-donation. The living donor registry is an ongoing effort, and the goal is to continue to collect data on living organ donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living organ donors post-donation will continue to provide useful information to transplant programs for their future donor selection process and to aid potential