required in that progress report is specified in section 4(f) of the AT Act.

Section 8 Requirements Necessitating Collection

Section 8(d) of the AT Act requires that ACL submit to Congress an annual report on the activities identified in the State Plan for AT and an analysis of the progress of the States and Territories in meeting their measurable goals. The State Plan for AT must include a compilation and summary of the activities conducted under section 4(f). In order to make this possible, States and Territories must provide their data uniformly. This State Plan for AT instrument was developed to ensure that all 56 States and Territories report data in a consistent manner in alignment with the requirements of section 4(f).

The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows: Fifty-six grantees report to ACL using the web-based data collection system. A workgroup of grantees estimated that the average amount of time required to complete all responses to the data collection instrument is 73 hours annually. The burden estimates affect the reporting responsibilities of the Statewide AT Programs, and the directors were chosen to represent the diversity of the 56 programs based on regions of the country, sizes of the programs, types of agencies operating the programs, and whether the director is an individual with a disability. The estimated response burden includes time to review the instructions, gather existing information, and complete and review the data entries.

a. *Number of respondents*: 56.

b. *Frequency of response*: 1.

c. *Total annual responses (a × b):* 56.

d. *Hours per response*: 73.

e. *Total burden hours (c × d)*: 4,088.

Dated: March 20, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–06366 Filed 3–25–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2179]

Phillip Leonowens: 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 Phillip Leonowens 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. Leonowens was convicted of one felony count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. Leonowens' conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Leonowens 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 December 31, 2023 (30 days after receipt of the notice), Mr. Leonowens had not responded. Mr. Leonowens'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, 2024.

ADDRESSES: Any application by Mr. Leonowens 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–2179. 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. 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. Leonowens was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Western District of Michigan, when the court 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. 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 and Plea Agreement from Mr. Leonowens' case, filed on April 27, 2022, and April 28, 2022, respectively, Brendon Gagne owned and operated *www.ExpressPCT.com,* which sold misbranded prescription drugs, obtained from overseas suppliers, to customers in the United States without requiring a prescription. In exchange for obtaining Modafinil for himself, Mr. Leonowens conspired with Brendon Gagne and agreed to receive, repackage, and reship prescription drugs that Mr. Leonowens would receive from co-conspirators outside of the United States that were purchased by customers on the website *www.ExpressPCT.com.* Mr. Leonowens received approximately four packages containing bulk quantities of prescription drugs which were all shipped from overseas, including from Germany, India, and Singapore. Each time Mr. Leonowens received a package, he removed some Modafinil for himself and then sent the rest of the drugs to others. In his plea agreement, Mr. Leonowens acknowledged that he knew that receiving and reshipping prescription drugs in this manner was illegal. Mr. Leonowens also recruited others to join in the scheme by also receiving and reshipping misbranded prescription drugs from overseas suppliers. In exchange for his participation in the scheme, Mr. Leonowens received free or discounted prescription drugs.

As a result of this conviction, FDA sent Mr. Leonowens, by United Parcel Service, 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. Leonowens' 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 misbranded 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. Leonowens' offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Leonowens 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. Leonowens received the proposal and notice of opportunity for a hearing at his residence on December 1, 2023. Mr. Leonowens 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. Leonowens 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. Leonowens 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. Leonowens is a prohibited act.

Dated: March 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06287 Filed 3–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2853]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled ''Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St, North Bethesda, MD 20852, *301–796–8867, PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 26, 2024, the Agency submitted a proposed collection of information entitled ''Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.