Produce Safety Branch 2 (DCSKDC2)
Produce Safety Branch 3 (DCSKDC3)
Office of Import Operations (DCSL)
Division of Targeting and Analysis (DCSLA)
Division of Import Operations (DCSLB)
Import Operations Branch (DCSLB1)
Import Compliance Branch (DCSLB2)
Division of Analysis and Program Evaluation (DCSLC)
Program Development Branch (DCSLC1)
Import Technical Assistance Branch (DCSLC2)
Division of Southwest Imports (DCSLD)
Southwest Import Investigations Branch (DCSLD1)
Southwest Import Compliance Branch (DCSLD2)
Division of Southeast Imports (DCSLE)
Southeast Import Investigations Branch 1 (DCSLE1)
Southeast Import Investigations Branch 2 (DCSLE2)
Southeast Import Compliance Branch (DCSLE3)
Division of Northeast Imports (DCSLF)
Northeast Import Investigations Branch (DCSLF1)
Northeast Import Compliance Branch (DCSLF2)
Division of Northern Border Imports (DCSLG)
Northern Border Import Investigations Branch 1 (DCSLG1)
Northern Border Import Investigations Branch 2 (DCSLG2)
Northern Border Import Compliance Branch (DCSLG3)
Division of West Coast Imports (DCSLH)
West Coast Import Investigations Branch (DCSLH1)
West Coast Import Compliance Branch (DCSLH2)
Division of Planning and Public Response (DCSLI)
Office of Medical Device and Radiological Health Inspectorate (DCSM)
Division of Mammography and Radiological Health Inspectorate (DCSMA)
Mammography Operations Branch 1 (DCSMA1)
Mammography Operations Branch 2 (DCSMA2)
Division of Medical Device and Radiological Health Inspectorate I (DCSMB)
Medical Device and Radiological Health Investigations Branch 1 (DCSMB1)
Medical Device and Radiological Health Investigations Branch 2 (DCSMB2)
Medical Device and Radiological Health Investigations Branch 3 (DCSMB3)
Medical Device and Radiological Health Investigations Branch 4 (DCSMB4)
Division of Medical Device and Radiological Health Inspectorate II (DCSMC)
Medical Device and Radiological Health Investigations Branch 1 (DCSMC1)
Medical Device and Radiological Health Investigations Branch 2 (DCSMC2)
Medical Device and Radiological Health Investigations Branch 3 (DCSMC3)
Medical Device and Radiological Health Investigations Branch 4 (DCSMC4)
Medical Device and Radiological Health Investigations Branch 5 (DCSMC5)
Division of Medical Device and Radiological Health Inspectorate III (DCSMD)
Medical Device and Radiological Health Investigations Branch 1 (DCSMD1)
Medical Device and Radiological Health Investigations Branch 2 (DCSMD2)
Medical Device and Radiological Health Investigations Branch 3 (DCSMD3)
Medical Device and Radiological Health Investigations Branch 4 (DCSMD4)
Medical Device and Radiological Health Investigations Branch 5 (DCSMD5)
Division of Medical Device and Radiological Health Global Operations (DCSME)
Medical Device and Radiological Health Foreign Operations Branch (DCSME1)
Medical Device and Radiological Health Operations Branch (DCSME2)
Medical Device and Radiological Health Risk Mitigation and Response Branch (DCSME3)
Division of Medical Device and Radiological Health Inspectorate IV (DCSMF)
Medical Device and Radiological Health Investigations Branch 1 (DCSMF1)
Medical Device and Radiological Health Investigations Branch 2 (DCSMF2)
Medical Device and Radiological Health Investigations Branch 3 (DCSMF3)
Medical Device and Radiological Health Investigations Branch 4 (DCSMF4)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2024–11893 Filed 5–30–24; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5345]

Michael Terry Little: 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 Michael Terry Little 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. Little was convicted of one felony count under Federal law for introduction of unapproved new drugs in interstate commerce. The factual basis supporting Mr. Little's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Little 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 March 13, 2024 (30 days after receipt of the notice), Mr. Little had not responded. Mr. Little'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 June 3, 2024.

ADDRESSES: Any application by Mr. Little for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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–5345. 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, 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 November 7, 2023, Mr. Little was convicted as defined in section 306(l)(1) of the FD&C Act, in the U. S. District Court for the District of Idaho when the court accepted his plea of guilty and entered judgment against him for the offense of Introduction of Unapproved New Drugs in Interstate Commerce in violation of 21 U.S.C. 331(d) and 333(a)(2) (sections 301(d) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows: as charged in the Information and stated in the Plea Agreement, beginning in or about March 2018, and continuing to on or about January 2022, Mr. Little ran a business selling Selective Androgen Receptor Modulators (SARMs). SARMs are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. SARMs are new drugs under the FD&C Act that have not been reviewed by FDA for safety and effectiveness and have not been approved for marketing in the United States. Mr. Little primarily sold his SARM products via the website https://sarm.tech, under the name SARMTECH. Mr. Little imported the bulk ingredients from China which he then processed at his business location in Idaho. At Mr. Little's business location he used the imported bulk ingredients to manufacture the SARM products and he encapsulated, bottled, and prepared the products for shipment to his customers. To avoid government seizures of SARMs shipped to other countries, Mr. Little offered a stealth shipping option for an additional fee that intentionally mispackaged and falsely declared SARMs shipments as vitamins and supplements. Mr. Little sold at least $4,499,197.46 worth of SARMs between March 2018 and January 2022.

FDA sent Mr. Little, by certified mail, on February 5, 2024, 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. Little's felony conviction under Federal law for Introduction of Unapproved New Drugs in Interstate Commerce in violation of 21 U.S.C. 331(d) and 333(a)(2), was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Little illegally imported bulk ingredients for SARMs from China which he used as components to manufacture unapproved new drugs that he then distributed for sale to his customers. 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. Little's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Little 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. Little received the proposal and notice of opportunity for a hearing on February 12, 2024. Mr. Little 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. Michael Terry Little 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. Little 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, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Little is a prohibited act.

Dated: May 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12066 Filed 5–31–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0945–0005]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 3, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov, PRA@hhs.gov,* or by calling (202) 264–0041.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0945–0005 and project title for reference to Sherrette A. Funn, the Reports Clearance Officer, email *Sherrette.Funn@hhs.gov, PRA@hhs.gov,* or call (202) 264–0041.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HIPAA Audit Review Survey.

Type of Collection: Reinstatement with Change of Previously Approved Collection.

OMB No. 0945–0005: Office for Civil Rights (OCR)—Health Information Privacy Division.

Abstract: This information collection consists of 39 online survey questions that will be sent to 207 covered entities and business associates that participated in the 2016–2017 OCR HIPAA Audits.

The survey will gather information relating to the effect of the audits on the audited entities and the entities' opinions about the audit process.

OCR is conducting a review of the 2016–2017 HIPAA Audits to determine its efficacy in assessing the HIPAA compliance efforts of covered entities.

As part of that review, the online survey will be used to:

- Measure the effect of the 2016–2017 HIPAA Audits on covered entities' and business associates' subsequent actions to comply with the HIPAA Rules.
- Provide entities with an opportunity to give feedback on the Audit and its features, such as the helpfulness of HHS' guidance materials and communications, the utility of the online submission portal, whether the Audit helped improve entity compliance, and the entities' responses to the Audit-report findings and recommendations.
- Provide OCR with information on the burden imposed on entities to collect audit-related documents and to respond to audit-related requests; and
- Seek feedback on the effect of the HIPAA Audit program on the entities' day-to-day business operations. The information, opinions, and comments collected using the online survey will be used to improve future OCR HIPAA Audits.

Type of Respondent: Privacy Officers, Security Officers, and/or Administrators of HIPAA covered entities and business associates.

ANNUALIZED BURDEN HOUR TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Covered Entity Privacy and Security Officer(s) or Administrators	166	1	45/60	124.5
Business Associate Privacy and Security Officer(s) or Administrators	41	1	45/60	30.75
Total	207			155.25

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–12083 Filed 5–31–24; 8:45 am]

BILLING CODE 4153–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0260]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 2, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0260–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and