21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-Submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
822	Postmarket Surveillance of Medical Devices	0910–0449
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130
601	Biologics License Application	0910–0338
803	Medical Device Reporting	0910–0437
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
800, 801, 809, and 830	Medical Device Labeling Requirements; Unique Device Identification.	0910–0485
860	Reclassification Petition for Medical Devices	0910–0138
''Emergency Use Authorization of Medical Products and Related Authorities''.	EUA	0910–0595

Dated: December 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27852 Filed 12–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2058]

James Funaro: 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 James Funaro 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. Funaro was convicted of one felony count under Federal law for conspiracy to launder money. The factual basis supporting Mr. Funaro's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Funaro 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 October 11, 2023 (30 days after receipt of the notice), Mr. Funaro had not responded. Mr. Funaro'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 December 19, 2023.

ADDRESSES: Any application by Mr. Funaro 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–2058. 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 February 27, 2023, Mr. Funaro was convicted, as defined in section 306(l)(1) of the 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 conspiracy to launder money in violation of 18 U.S.C. 1956(h), 1956(a)(1)(A)(i), and 1956(a)(1)(B)(i). 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 indictment and plea agreement in Mr. Funaro's case, filed on March 1, 2022, and July 29, 2022, respectively, beginning in or about 2018 and continuing until in or about October 2021 several individuals ran a website, *www.ExpressPCT.com,* which sold misbranded prescription drugs as well as some Schedule III and Schedule IV controlled substances in the United States without requiring a prescription. The drugs were manufactured overseas and then shipped in bulk to the United States to domestic redistributors. The packages did not declare their illicit contents and instead took steps to conceal their true nature. Once the packages entered the United States, the redistributors sent the bulk orders to second tier U.S. based distributors who then finally shipped the drugs to the customers, making the purchasers think their drugs came from the United States and not from overseas. Part of Mr. Funaro's role in the scheme was to route some of the customer payments for the misbranded drugs made through *www.ExpressPCT.com* through a series of accounts in an effort to conceal the source of the funds. Mr. Funaro also converted proceeds into cryptocurrency which he used, in part, to pay redistributors of the misbranded drugs. Mr. Funaro also sent some of the funds to various pharmaceutical companies in India in order to purchase additional drugs and thus continue the scheme.

As a result of this conviction, FDA sent Mr. Funaro, by certified mail, on September 6, 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. Funaro's felony conviction under Federal law for conspiracy to launder money in violation of 18 U.S.C. 1956(h), 1956(a)(1)(A)(i), and 1956(a)(1)(B)(i), 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. Funaro's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Funaro 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. Funaro received the proposal and notice of opportunity for a hearing on September 11, 2023. Mr. Funaro 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. James Funaro 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. Funaro 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. Funaro is a prohibited act.

Dated: December 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27854 Filed 12–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2080]

Jeremy Walenty: 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 (the FD&C Act) debarring Jeremy Walenty 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. Walenty was convicted of one felony count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. Walenty's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Walenty 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 October 15, 2023 (30 days after receipt of the notice), Mr. Walenty had not responded. Mr. Walenty's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is effective December 19, 2023.

ADDRESSES: Any application by Mr. Walenty for termination of debarment