System No. 09–80–0381; 87 FR 3553 (January 24, 2022).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0526]

David Elias Mendoza: 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 David Elias Mendoza 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. Mendoza engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Mr. Mendoza 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 28, 2022 (30 days after receipt of the notice), Mr. Mendoza had not responded. Mr. Mendoza's failure to respond and request a hearing within the timeframe prescribed by regulation constitutes a waiver of his right to a hearing and any contentions concerning this matter.

DATES: This order is applicable November 15, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, 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, Division of Enforcement (ELEM–4144), 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)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer) that are not designated in an authorized electronic data interchange system as products regulated by FDA.

After an investigation, FDA discovered that Mr. Mendoza has engaged in numerous instances of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that were not designated in an authorized electronic data interchange system as products that are regulated by FDA; all the parcels containing the misbranded drugs serving as the basis for this action, described in further detail below, were intercepted by FDA at the John F. Kennedy (JFK) International Mail Facility (IMF) and were addressed to Mr. Mendoza at one of two addresses connected to him.

On or about June 4, 2019, Mr. Mendoza offered for import a parcel that contained 250 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label and lacked adequate directions for use in its labeling. The product was refused entry on July 9, 2019.

On or about January 24, 2020, Mr. Mendoza offered for import a parcel that contained 250 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label and lacked adequate directions for use in its labeling. The product was refused entry on February 20, 2020.

On or about January 29, 2020, Mr. Mendoza offered for import a parcel that contained 250 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label and lacked adequate directions for use in its labeling. The product was refused entry on February 25, 2020.

On or about January 30, 2020, Mr. Mendoza offered for import a parcel that contained 270 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label and lacked adequate directions for use in its labeling. The product was refused entry on February 25, 2020.

On or about February 14, 2020, Mr. Mendoza offered for import a parcel that contained 330 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label and lacked adequate directions for use in its labeling. The product was refused entry on March 17, 2020.

On or about February 14, 2020, Mr. Mendoza offered for import a parcel that contained 250 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label and lacked adequate directions for use in its labeling. The product was refused entry on March 17, 2020.

On or about February 24, 2020, Mr. Mendoza offered for import a parcel that contained 250 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label and lacked adequate directions for use in its labeling. The product was refused entry on March 19, 2020.

On or about June 10, 2020, Mr. Mendoza offered for import a parcel that contained 300 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on July 10, 2020.

On or about June 10, 2020, Mr. Mendoza offered for import a parcel that contained 300 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on July 7, 2020.

On or about June 16, 2020, Mr. Mendoza offered for import a parcel that contained 300 tablets of CENFORCE–100, which was a misbranded drug because the product failed to contain adequate directions for use in its labeling. The product was refused entry on July 14, 2020.

On or about June 16, 2020, Mr. Mendoza offered for import a parcel that contained 320 tablets of CENFORCE–100, which was a misbranded drug

because the product failed to contain adequate directions for use in its labeling. The product was refused entry on July 14, 2020.

On or about June 18, 2020, Mr. Mendoza offered for import a parcel that contained 300 tablets of CENFORCE–100, which was a misbranded drug because the product was determined to be a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on July 15, 2020.

As a result of Mr. Mendoza's pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Mr. Mendoza, by certified mail on February 17, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug 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. Mendoza's pattern of conduct and concluded that his conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Mendoza of the proposed debarment and offered him an opportunity to request a hearing, providing 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. Mendoza received the proposal and notice of opportunity for a hearing on February 26, 2022. Mr. Mendoza 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)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. David Elias Mendoza has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct 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. Mendoza 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. Mendoza is a prohibited act.

Any application by Mr. Mendoza for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0526 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: November 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2778]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 15, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0298. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39

OMB Control Number 0910–0298—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) it conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the FD&C Act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) of the FD&C Act or an effective notification in accordance with section 409(a)(3)(B) of the FD&C Act.

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion. The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is