



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-1255]

#### Tuan Anh Tran: 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 Tuan Anh Tran 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. Tran 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. Tran was given notice of the proposed debarment and an opportunity to request a hearing to show why he should not be debarred. As of September 14, 2020 (30 days after receipt of the notice), Mr. Tran had not responded. Mr. Tran'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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**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-4029), 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](mailto: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), and the shipments are not designated in an entry in an authorized electronic data exchange system as products regulated by FDA.

After an investigation, FDA discovered that Mr. Tran has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action were intercepted by FDA at the John F. Kennedy International Mail Facility and were addressed to Mr. Tran at one of two addresses connected to him.

On or about April 12, 2019, Mr. Tran offered for import three parcels. The product contained in the first parcel was 210 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because the product was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on May 17, 2019. The product contained in the second parcel was 245 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because the product was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on May 17, 2019. The product contained in the third parcel was 245 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because the product was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on May 17, 2019.

On or about September 13, 2019, Mr. Tran offered for import four parcels. The product contained in the first parcel was 312 Kamagra Sildenafil Citrate Chewable Tablets and was a

misbranded drug because it was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on October 22, 2019. The product contained in the second parcel was 312 Kamagra Sildenafil Citrate Chewable Tablets and was a misbranded drug because it was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on October 22, 2019. The product contained in the third parcel was 196 packets (pieces) of Kamagra Sildenafil Citrate Jelly and was a misbranded drug because it was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on October 22, 2019. The product contained in the fourth parcel was 231 packets (pieces) of Kamagra Sildenafil Citrate Jelly and was a misbranded drug because it was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on October 22, 2019.

On or about September 26, 2019, Mr. Tran offered for import a parcel that was intercepted and processed by FDA. The product contained in the parcel was 196 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because it was a prescription drug product that failed to contain the “Rx-only” symbol on its label. The product was refused entry on October 29, 2019.

Because of this 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. Tran, by certified mail on August 7, 2020, a notice proposing to debar him for 5 years 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. Tran’s pattern of conduct and concluded that his conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Tran 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. Tran received the proposal and notice of opportunity for a hearing on August 15, 2020. Mr. Tran failed to request a hearing within the timeframe prescribed by regulation and, therefore, has 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. Tuan Anh Tran 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 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. Tran is debarred for 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. Tran is a prohibited act.

Any application by Mr. Tran for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-1255 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 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-26250 Filed: 11/27/2020 8:45 am; Publication Date: 11/30/2020]