4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1398]

Linda Godding: 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 Linda Godding 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 Ms. Godding was convicted of one felony count under Federal law for introducing or delivering for introduction a misbranded drug in interstate commerce. The factual basis supporting Ms. Godding's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Godding was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of September 29, 2022 (30 days after receipt of the notice), Ms. Godding had not responded. Ms. Godding's failure to respond and request a hearing constitutes a waiver of her 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-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 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)(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 June 10, 2022, Ms. Godding was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the District of Colorado, when the court entered judgment against her, after her plea of guilty, for the offense of introducing or delivering for introduction a misbranded drug in interstate commerce in violation of 21 U.S.C. 331(a) and 333(a)(2). 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 factual basis of the Plea Agreement in Ms. Godding's case, filed on January 27, 2022, and as set forth in the notice of proposed debarment, along with Mark Godding, she purchased the business Mighty Stacks, LLC in December 2016. Mighty Stacks, LLC did business as Blue Brain Boost and sold products through its website, bluebrainboost.com. Both before and after her acquisition of Mighty Stacks, LLC, the business sold products identified by FDA as unapproved new drugs and misbranded drugs. Ms. Godding leased warehouse space in Fort Collins, Colorado, where she stored and from which she shipped her products.

The Blue Brain Boost website identified all its products as "nootropics," a term given by those in the health supplements industry to chemicals often advertised as "smart drugs" and "cognitive enhancers." The Blue Brain Boost website provided information regarding its products that rendered those products "drugs" either because the website identified the products

as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man,” as “articles (other than food) intended to affect the structure or any function of the body of man,” or both (21 U.S.C. 321(g)(1)(B) and (C)). Ms. Godding, along with Mark Godding, purchased these nootropic products, identified by FDA as unapproved new drugs and misbranded drugs, from China and repackaged and distributed the products as supplements for consumer use.

Ms. Godding, along with Mark Godding, used e-commerce platforms to locate suppliers of the products. Ms. Godding had no knowledge of these products’ manufacturers’ practices, where or how the products were manufactured, the safety of those products, or that the products were what the suppliers alleged them to be, with the minor exception that Ms. Godding in rare cases had the products tested, sometimes after receiving safety complaints from her customers. The products Ms. Godding purchased and imported from foreign suppliers, predominantly from China, included, tianeptine sodium powder, adrafinil crystalline powder, aniracetam crystalline powder, nicotine USP solution in 100% glycol, IDRA-21, methylene blue solution, noopept crystalline powder, oxiracetam, phenibut hydrocholoride crystalline powder, coluracetam chrystalline powder, phenylpiracetam crystalline powder, pramiracetam, and sunifiram.

Ms. Godding knew that she was importing these products in violation of law. Ms. Godding, and Mark Godding, were in receipt of numerous Notice of FDA Action forms placing holds, noting detentions, or demanding return of nootropic products imported to the United States to be delivered to Ms. Godding and Mark Godding in Colorado for their clients. These notices informed Ms. Godding that the same nootropic products sold through Blue Brain Boost “are subject to refusal pursuant to the FD&C Act, Public Health Service Act, or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated.” Copies of these notices were located in Ms. Godding’s desk during an execution of a search warrant at the Godding’s warehouse.

Because Ms. Godding and Mark Godding knew it was illegal to import these products into the United States, the Goddings worked with international suppliers to conceal from Customs and Border Protection the true nature of these shipments. For example, Ms. Godding negotiated with Chinese suppliers to have the products shipped to Blue Brain Boost from U.S. warehouses rather than direct from China. It is common for foreign suppliers of illegal goods to ship their products to their own warehouses in the United States, identifying the products as intended for research or other authorized purposes to avoid Customs. Ms. Godding was also aware that foreign suppliers mislabeled products shipped to Blue Brain Boost to avoid Customs.

For example, on November 7, 2017, Ms. Godding emailed a testing laboratory representative to let him know that she was sending him 3 grams of tianeptine sodium for testing as she did not want to pay the supplier until she had the test results. She noted in her email that the product was coming to the laboratory with a different sender name and not from Blue Brain Boost, and labeled as, "Alpha GPC to get it thru customs." Ms. Godding also received emails from Chinese suppliers explaining how the suppliers changed the product name for easy shipment and customs clearance.

After purchasing and importing these products from foreign suppliers, Ms. Godding did, along with Mark Godding, repackage or caused others to repackage the products into Blue Brain Boost labeled containers intended for consumer use and Ms. Godding shipped them to customers using a shipping program. The Blue Brain Boost products were misbranded because they were drugs sold without any directions for use.

Undercover Federal agents from FDA's Office of Criminal Investigations (OCI) made undercover purchases from the Blue Brain Boost online store that were shipped, interstate, to Kansas from Colorado. In one of those purchases, the agents purchased 5 grams of "Tianeptine Sodium Powder" which arrived in a blue container marked only, "Tianeptine Sodium >99%" with the Blue Brain logo on one label on the on the lid and a second label on the side of the bottle reading only, "5 gm" and "18052408." There were no directions for use in the labels.

During the execution of a search warrant at the Godding's warehouse and office, Federal agents found a form from a Chinese tianeptine sodium supplier signed by Mark Godding which acknowledged: "The customer agrees that the Tianeptine Sodium bought or will buy from [the company in China] is not a dietary supplement ingredient defined under section 201(ff) of the Federal Food, Drug, and Cosmetic Act (The Act) (21 U.S.C. 321(ff)), and shall not use for products marketed as a dietary supplement (*sic*)."

As a result of this conviction, FDA sent Ms. Godding, by certified mail, on August 23, 2022, a notice proposing to debar her 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 Ms. Godding's felony conviction under Federal law for introducing or delivering for introduction a misbranded drug in interstate commerce in violation of sections 331(a) and 333(a)(2) of the FD&C Act, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally imported unapproved new drugs and misbranded drugs from foreign suppliers which she repackaged and sold to customers throughout 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 Ms. Godding's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Godding of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Godding received the proposal and notice of opportunity for a hearing on August 30, 2022. Ms. Godding failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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 Ms. Linda Godding 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, Ms. Godding 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 Ms. Godding is a prohibited act.

Any application by Ms. Godding for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2022-N-1398 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: January 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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