TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
226.42, 226.58, 226.80, 226.102, 226.110, and 226.115; Recordkeeping and maintenance of records for components used in the manufacture of the medicated premixes, laboratory controls, packaging and labeling, master formula and batch-production, distribution records and complaint files.	65	1,370	89,050	~1 hour	89,050

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Decimals rounded.

The burden we attribute to recordkeeping activities associated with the provisions in 21 CFR part 226 are assumed to be distributed among the individual elements and averaged among respondents. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12512 Filed 6–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3011]

Luis Anarbol Moran: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Luis Anarbol Moran 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. Moran was convicted of one felony count under Federal law for smuggling goods into the United States. The factual basis supporting Mr. Moran's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Moran 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 30, 2023 (30 days after receipt of the notice), Mr. Moran had not responded. Mr. Moran'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 12, 2023.

ADDRESSES: Any application by Mr. Moran 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–2022–N–3011. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' 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. 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 (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 July 22, 2022, Mr. Moran was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Southern District of Florida-West Palm Beach Division, when the court accepted his plea of guilty and entered judgment against him for the offense of smuggling goods into the United States, in violation of 18 U.S.C. 545. 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, filed on October 6, 2021, and the plea agreement, filed on April 14, 2022, in Mr. Moran's case, Jhanna Novikov agreed to treat the facial wrinkles of an individual who was an undercover investigator with the Florida Department of Health with ''fillers'' for $600 and ''Botox'' for $300. BOTOX, or botulinum neurotoxin Type A, is the most well-known neurotoxin approved by FDA to treat facial wrinkles. On August 10, 2018, the investigator returned to Ms. Novikov's residence for her ''Botox'' treatment, and as Ms. Novikov made preparations and drew a liquid into a syringe, agents from FDA's Office of Criminal Investigations (OCI) entered and took control of her residence. After obtaining a warrant, OCI agents searched Ms. Novikov's home. Agents seized various vials of white powder from Ms. Novikov's residence, including two labeled ''NEUROXIN Botulinum Toxin Type A,'' 14 labeled ''CASPIS,'' and 1 with no label. Analysis by the FDA Forensic Chemistry Center determined that the two NEUROXIN vials, a sample of four of the CASPIS vials, and the unlabeled vial all contained botulinum toxin, the active ingredient in BOTOX; however, a search of FDA records revealed that these drugs had not been approved by FDA and were unapproved new drugs as well as misbranded drugs. Agents did not find any BOTOX or other FDA-approved drugs containing botulinum toxin in Ms. Novikov's home.

During the search of Ms. Novikov's residence, agents seized her cell phone and subsequently conducted a computer forensic examination of the phone. The examination revealed that, from August 10, 2016 through June 26, 2018, Mr. Moran exchanged messages with Ms. Novikov about the products he sold her, referring to them as ''botox,'' ''bx,'' and ''tox.'' In some cases, Mr. Moran's messages discussed sending packages to Ms. Novikov from outside the United States. For example, in response to Ms. Novikov's October 3, 2016, inquiry about a package, Mr. Moran replied that ''[i]t was in customs.'' In another instance on April 18, 2017, Ms. Novikov wrote to Mr. Moran that a package had been ''opened at customs'' but ''all fine[.]'' In response, Mr. Moran stated he had ''put it as anti dandruff.'' In another exchange, on June 22, 2018, Ms. Novikov messaged Mr. Moran, ''I need bx'' and agreed to pay $1,200, plus $100 shipping. Ms. Novikov sent Mr. Moran a photograph of a deposit slip on June 25, 2018, indicating that $1,300 had been deposited into a bank account. That same day, Mr. Moran sent Ms. Novikov a photograph of a shipping confirmation for a package he shipped to her from Mexico. On June 26, 2018, Ms. Novikov sent Mr. Moran a message asking, ''Why Caspis? They like Neuroxin better.'' Mr. Moran replied, ''is for customs . . . issues'' and offered to send Ms. Novikov ''Neuroxin labels'' and ''boxes and stickers[,]'' but she declined.

As a result of this conviction, FDA sent Mr. Moran, by certified mail, on February 9, 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. Moran's felony conviction under Federal law for smuggling goods into the United States, in violation of 18 U.S.C. 545, was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported unapproved new drugs containing botulinum toxin for use in treatments conducted by others for money. 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. Moran's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Moran 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. Moran received the proposal and notice of opportunity for a hearing at his residence on February 28, 2023. Mr. Moran 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. Luis Anarbol Moran 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. Moran 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. Moran is a prohibited act.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12487 Filed 6–9–23; 8:45 am]

BILLING CODE 4164–01–P