draft guidance for industry that appeared in the **Federal Register** of November 30, 2022. In that notice, FDA requested comments on draft guidance for industry (GFI) #276 entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published November 30, 2022 (87 FR 73560). Submit either electronic or written comments by May 1, 2023, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–2899 for ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs.'' Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 comments 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 to read background documents or the electronic and written/paper comments received, 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.

FOR FURTHER INFORMATION CONTACT: Steven Fleischer, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0809, *Steven.Fleischer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 30, 2022, FDA published a notice announcing the availability of a draft guidance for industry entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs,'' and requesting comments on the proposed GFI.

Interested persons were originally given until January 30, 2023, to comment on the document. The Agency has received a request for an extension of the comment period. The request stated that an additional 90 days would allow interested parties to thoroughly consider the request for input. FDA has considered the request and is extending the comment period for the request for comments for 90 days, until May 1, 2023. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01031 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1384]

Mark 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 Mark 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 Mr. 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 Mr. Godding's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Godding 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

September 29, 2022 (30 days after receipt of the notice), Mr. Godding had not responded. Mr. Godding'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 January 20, 2023.

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)(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 May 20, 2022, Mr. 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 him, after his 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 Mr. Godding's case, filed on January 26, 2022, and as set forth in the notice of proposed debarment, along with Linda Godding, he 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 his acquisition of Mighty Stacks, LLC, the business sold products identified by FDA as unapproved new drugs and misbranded drugs. Mr. Godding leased warehouse space in Fort Collins, Colorado, where he stored and from which he shipped his products.

The Blue Brain Boost website identified all of 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)). Mr. Godding, along with Linda 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.

Mr. Godding, along with Linda Godding, used e-commerce platforms to locate suppliers of the products. Mr. 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 Mr. Godding in rare cases had the products tested, sometimes after receiving safety complaints from his customers. The products Mr. 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.

Mr. Godding knew that he was importing these products in violation of law. Mr. Godding, and Linda 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 Mr. Godding and Linda Godding in Colorado for their clients. These notices informed Mr. 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 Linda Godding's desk during an execution of a search warrant at the Godding's warehouse.

Because Mr. Godding and Linda 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, Linda 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.

Linda Godding was also aware that foreign suppliers mislabeled products shipped to Blue Brain Boost to avoid Customs. For example, on November 7, 2017, Linda 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.'' Linda 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, Mr. Godding did, along with Linda Godding, repackage or caused others to repackage the products into Blue Brain Boost labeled containers intended for consumer use and Mr. 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 the FDA's Office of Criminal Investigations 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 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 Mr. Godding that 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 Mr. Godding, by certified mail, on August 23, 2022, 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. Godding's felony conviction under Federal law for Introducing or Delivering for Introduction a Misbranded Drug in Interstate Commerce in violation of 21 U.S.C. 331(a) and 333(a)(2) was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported unapproved new drugs and misbranded drugs from foreign suppliers that he 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 Mr. Godding's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Godding 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. Godding received the proposal and notice of opportunity for a hearing on August 30, 2022. Mr. Godding 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. Mark 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, Mr. 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 Mr. Godding is a prohibited act.

Any application by Mr. Godding for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2022–N–1384 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.

[FR Doc. 2023–00999 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2395]

Mpox: Development of Drugs and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Mpox: Development of Drugs and Biological Products.'' FDA is issuing this guidance to support sponsors in their development of drugs and biological products for mpox.

DATES: Submit either electronic or written comments on the draft guidance by March 21, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–2395 for ''Mpox: Development of Drugs and Biological Products.'' Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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