''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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kimberly Struble, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Building 22, Room 6374, Silver Spring, MD 20993, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Mpox: Development of Drugs and Biological Products.''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. This guidance provides nonclinical, virology, and clinical considerations for mpox drug and biological product development programs, with a focus on recommendations to support initiation of clinical trials. Preventive vaccines are not addressed in this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Mpox: Development of Drugs and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 for investigational new drug applications and clinical trials have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for new drug application submissions have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for biologic new drug applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01029 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–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 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 *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.

[FR Doc. 2023–00997 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, January 24, 2023, 12:00 p.m. to January 24, 2023, 4:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD, 20852, which was published in the **Federal Register** on December 30, 2022, FR Doc 2022–28446, 87 FR 80554.

This notice is being amended to change the meeting date from January 24, 2023, to February 2, 2023. Meeting location and time remain the same. The meeting is closed to the public.

Dated: January 13, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–01018 Filed 1–19–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Small Cell Lung Cancer Subtyping Using Plasma Cell-Free Nucleosomes

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Yissum Research and Development (''Yissum''), the technology transfer company of the Hebrew University of Jerusalem, a non-profit research institution located in Jerusalem, Israel for NCI's rights to the patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before February 6, 2023 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michaela McCrary, Ph.D., Licensing and Patenting Manager, NCI Technology Transfer Center, at: Email: *michaela.mccrary@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Yissum: United States Provisional Patent Application No. 63/342,763, filed May 17, 2022 and entitled ''SMALL CELL LUNG CANCER SUBTYPING USING PLASMA CELL–FREE NUCELOSOMES'' [HHS Reference No. E–172–2022–0–US–01].

The patent rights in these inventions have been assigned to the Government of the United States of America and Yissum. The prospective license will be for the purpose of consolidating the patent rights to Yissum, the co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective patent license territory will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by Yissum will be subject to the provisions of 37 CFR part 401 and 404.

This technology discloses a non-invasive method to molecularly subtype SCLC from plasma samples using chromatin immunoprecipitation of cell-free nucleosomes carrying active chromatin modification followed by sequencing (cfChIP–seq).

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will include terms for the sharing of royalty income with NCI from commercial sublicenses of the patent rights. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license