DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0619]

Advisory Committee; Gastrointestinal Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Gastrointestinal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Gastrointestinal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 3, 2024, expiration date.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Rhea Bhatt, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–9001, email: *GIDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Gastrointestinal Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/gastrointestinal-drugs-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to The Committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: May 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10040 Filed 5–10–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1992]

Marwan Massouh; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying Marwan Massouh's (Dr. Massouh's) request for a hearing and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. Massouh for 3 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Massouh was convicted of a misdemeanor under Federal law for causing the introduction or delivery for introduction into interstate commerce of drugs that were misbranded under the FD&C Act. Additionally, FDA finds that the conduct underlying Dr. Massouh's conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Dr. Massouh's debarment, FDA considered the relevant factors listed in the FD&C Act. Dr. Massouh failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable May 11, 2022.

ADDRESSES: Any application for termination of debarment by Dr. Massouh under section 306(d) of the FD&C Act (application) 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

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 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–2018–N–1992. An application will be placed in the docket and, unless 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, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that (1) the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and (2) the conduct underlying the conviction undermines the process for the regulation of drugs.

In September 2013, Dr. Massouh pled guilty to a misdemeanor for introducing a misbranded drug into interstate commerce, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)). On October 16, 2013, the U.S. District Court for the Northern District of Ohio entered a judgment of conviction against Dr. Massouh for his violation of section 301(a) and sentenced him to 1 year of probation. According to the criminal information to which Dr. Massouh pled guilty, between January 3, 2006, and March 31, 2009, Dr. Massouh, an oncologist, purchased and received oncology drugs from a drug distributor located in Canada. Dr. Massouh's actions caused the introduction into interstate commerce of drugs that were misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) because their labeling did not bear adequate directions for use.

By letter dated July 13, 2018, FDA's Office of Regulatory Affairs (ORA) notified Dr. Massouh of a proposal to debar him for 3 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal explained that FDA based the proposed debarment on his misdemeanor conviction. The proposal outlined findings concerning the four relevant factors that ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of the offense under section 306(c)(3)(A); (2) the nature and extent of management participation in the offense under section 306(c)(3)(B); (3) the nature and extent of voluntary steps to mitigate the impact on the public under section 306(c)(3)(C); and (4) prior convictions under the FD&C Act or other acts involving matters within FDA's jurisdiction under section 306(c)(3)(F). ORA found that the first two were unfavorable factors and the last two were favorable factors for Dr. Massouh. The notice concluded that ''the unfavorable factors cumulatively outweigh the favorable factors and that debarment is appropriate.''

The proposal offered Dr. Massouh the opportunity to request a hearing and provided him 30 days from the date of receipt of the letter to file the request and 60 days from the date of receipt of the letter to support his request with information sufficient to justify a hearing. In a submission dated August 17, 2018, through counsel, Dr. Massouh ''request[ed] a hearing relative to the Food and Drug Administration's Notice of Opportunity for Hearing'' but did not include information to support his request. Further, Dr. Massouh did not state whether information justifying the hearing request would be forthcoming. However, more than 60 days have elapsed since Dr. Massouh's receipt of ORA's letter, and he has not filed any information, or any legal or policy arguments, to support his request.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Acting Chief Scientist has considered Dr. Massouh's request for a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

Inasmuch as Dr. Massouh has not presented any information to support his hearing request, the Acting Chief Scientist concludes that Dr. Massouh has failed to raise a genuine and substantial issue of fact requiring a hearing. Therefore, the Acting Chief Scientist denies Dr. Massouh's request for a hearing. Further, Dr. Massouh has not presented any arguments concerning whether debarment is appropriate for his conviction or whether the proposed debarment period is appropriate. Based on the factual findings in the proposal to debar, the Acting Chief Scientist finds that a 3-year debarment period is appropriate.

II. Findings and Order

Therefore, the Acting Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under the authority delegated to her by the Commissioner of Food and Drugs, finds that (1) Dr. Massouh has been convicted of a misdemeanor under Federal law for causing the introduction into interstate commerce of prescription drugs that were misbranded under the FD&C Act and (2) that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA considered

the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a 3-year debarment is appropriate.

As a result of the foregoing findings, Dr. Massouh is debarred for 3 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (DATE of NOTICE), (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug application who knowingly uses the services of Dr. Massouh, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Massouh, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Massouh during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: April 21, 2022.

Jacqueline A. O'Shaughnessy,

Acting Chief Scientist.

[FR Doc. 2022–10096 Filed 5–10–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Development and Disease Study Section.

Date: June 1–3, 2022.

Time: 10:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aruna K. Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, (301) 435–6809, *beheraak@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Interdisciplinary Clinical Care in Specialty Care Settings Study Section.

Date: June 2–3, 2022.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Abu Saleh Mohammad Abdullah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Kidney, Nutrition, Obesity and Diabetes Study Section.

Date: June 2–3, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Steven Michael Frenk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, (301) 480–8665, *frenksm@mail.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Addiction Risks and Mechanisms Study Section.

Date: June 6–7, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Arthritis, Connective Tissue and Skin Study Section.

Date: June 8–9, 2022.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert Gersch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 867–5309, *robert.gersch@nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Development—1 Study Section.

Date: June 8–9, 2022.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Zubaida Saifudeen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 827–3029, *zubaida.saifudeen@nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Atherosclerosis and Vascular Inflammation Study Section.

Date: June 9–10, 2022.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, (301) 435–1206, *komissar@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Intercellular Interactions, Cell Signaling, and Aging.

Date: June 9, 2022.

Time: 11:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas Y. Cho, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Rm. 5144, MSC 7840, Bethesda, MD 20892, (301) 402–4179, *thomas.cho@nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: June 9–10, 2022.

Time: 1:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, *hargravesl@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–20–