

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.

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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