

Dated: March 5, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0008]

Advisory Committee; Gastrointestinal Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of 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 March 3, 2022.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jay Fajiculay, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: GIDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3, 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.

Pursuant to its Charter, 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. Almost all non-Federal members of this committee serve as Special Government Employees. 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 document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: March 4, 2020.

Lowell J. Schiller,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6644]

Fiscal Year 2020 Generic Drug Regulatory Science Initiatives; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “FY 2020 Generic Drug Regulatory Science Initiatives.” The purpose of the public workshop is to provide an overview of the status of regulatory science initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2017 (GDUFA II) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2021 regulatory science initiatives.

DATES: The public workshop will be held on May 4, 2020, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by June 4, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Bldg. 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 4, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 4, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2017-N-6644 for "FY 2020 Generic Drug Regulatory Science Initiatives; Public Workshop; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- **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.

FOR FURTHER INFORMATION CONTACT:

Stephanie Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4732, Silver Spring, MD 20993, 240-402-7960, Stephanie.Choi@fda.hhs.gov; or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240-402-7957, Robert.Lionberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments of 2012 (GDUFA I) (Pub. L. 112-144). GDUFA I was designed to enhance public access to safe, high-quality generic drugs and to modernize the generic drug program. To support this goal, FDA agreed in the GDUFA I commitment letter¹ to work with industry and interested stakeholders on identifying regulatory science initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA I was reauthorized until September 2022 through GDUFA II (Pub. L. 115-52). In

the GDUFA II commitment letter,² FDA agreed to conduct annual public workshops "to solicit input from industry and stakeholders for inclusion in an annual list of GDUFA II [r]egulatory [s]cience initiatives." The public workshop scheduled for May 4, 2020, seeks to fulfill this agreement.

II. Topics for Discussion at the Public Workshop

The purpose of the public workshop is to obtain input from industry and other interested stakeholders on the identification of generic drug regulatory science initiatives for FY 2021.

FDA is particularly interested in receiving input in the following four topic areas:

1. Post-market surveillance of generic drugs
2. Drug-device combination products
3. In vitro bioequivalence methods
4. Data analysis and model-based bioequivalence

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2021 regulatory science initiatives. Information concerning the regulatory science initiatives for generic drugs can be found at <https://www.fda.gov/gdufaregscience>.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to GDUFARegulatoryScience@fda.hhs.gov. For planning purposes, please also indicate in the email: (1) Whether attendance will be by webcast or in person and (2) the desired breakout session of attendance. Four breakout sessions will be held concurrently in the afternoon based on the following 4 areas: (1) Post-market surveillance of generic drugs, (2) drug-device combination drug products, (3) in-vitro bioequivalence methods, and (4) data analysis and model-based bioequivalence.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by April 3, 2020, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will

¹ The GDUFA I commitment letter is available at <https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>.

² The GDUFA II commitment letter is available at <https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf>.

receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Stephanie Choi (see **FOR FURTHER INFORMATION CONTACT**) no later than April 3, 2020.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session for a specific breakout session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments (and requests to participate in the focused sessions). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 10, 2020. All requests to make oral presentations must be received by the close of registration on April 3, 2020, midnight Eastern Time. If selected for presentation, any presentation materials must be emailed to GDUFARegulatoryScience@fda.hhs.gov no later than April 24, 2020, midnight Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Persons attending FDA's workshops are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Please register online by April 3, 2020, midnight Eastern Time to attend the workshop remotely. Please note that remote attendees will not be able to speak or make presentations during the public comment session or during any other session of the workshop. To join the main sessions of the workshop via the webcast, please go to <https://collaboration.fda.gov/gdrsipw2020/>. Webcast information for the four breakout sessions will be provided separately via email upon successful registration.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document

publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov> or at <https://www.fda.gov/gdufaregscience>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/gdufaregscience>.

Dated: March 4, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Declaration

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined, pursuant to his authority under section 564 of the FD&C Act, that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 2, 2020.

FOR FURTHER INFORMATION CONTACT:

Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA), authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear ("CBRN") agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security, pursuant to section 319F-2 of the Public Health Service (PHS) Act,¹ sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.²

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances

¹ 42 U.S.C. 247d-6b.

² As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113-5, the Secretary may make determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.