American Pathologists; National Association of Medical Examiners; MD Anderson Cancer Center);

- Kimberley Hanson, MD, MHS, FIDSA (Infectious Diseases Society of America);
- Michele M. Schoonmaker, Ph.D. (Advanced Medical Technology Association);

Terms have expired (or will expire during Calendar Year (CY) 2019) for the following CDLT Panel members (parenthetical denotes nomination source(s)):

- Geoffrey Baird, M.D., Ph.D. (Seattle Children's Hospital);
- Raju Kucherlapati, Ph.D. (Coalition of 21st Century Medicine);
- Bryan A. Loy, M.D., M.B.A. (Humana, Inc.);
- Gail Marcus, Ph.D., M.B.A., M.S.E. (Self-Nomination);
- Carl Morrison, M.D., D.V.M. (The United States Congress; Roswell Park Cancer Center);
- Rebecca Sutphen, M.D. (Self-Nomination; Informed Medical Decisions);

## III. Copies of the Charter

The Secretary's Charter for the Medicare Advisory Panel on CDLTs is available on the CMS website at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.* Also, copies of the charter can be obtained by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

## IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required.

Dated: June 11, 2019.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2019–13900 Filed 6–27–19; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–2452]**

## Endpoints for Drug Development in Heart Failure; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled ''Endpoints for Drug Development in Heart Failure.'' The purpose of this public meeting is to bring the stakeholder community together to discuss clinical endpoints for trials in heart failure that could be used to support FDA approval of drugs. The workshop will focus on endpoints related to symptoms and physical function. In addition, there will be discussion of the need to assess mortality effects of drugs under development for heart failure.

**DATES:** The public workshop will be held on Friday, July 26, 2019, from 9 a.m. to 4 p.m. 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, Rm. 1503 (the Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 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.*

**FOR FURTHER INFORMATION CONTACT:** Meg Pease-Fye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4115, Silver Spring, MD, 20993–0002, 301–796–1130, *Meg.PeaseFye@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing a public workshop regarding clinical endpoints for trials in heart failure that could be used to support FDA approval of drugs. FDA is convening this public workshop to discuss the Agency's current thinking with expert stakeholders and to consider public comments.

## II. Topics for Discussion at the Public Workshop

FDA is interested in soliciting feedback on a number of topics:

1. Consider and discuss endpoints related to symptoms and physical function, *e.g.,* patient-reported outcome instruments, exercise tests, data from electronic monitors;
2. Consider the best ways to count multiple hospitalizations;
3. Discuss when the nature and clinical importance of a treatment effect for a particular endpoint may justify deferral or omission of outcomes studies;
4. In setting an upper bound for a mortality risk to be ruled out, discuss how the boundary may be influenced by a drug's demonstrated benefits and risks;
5. Discuss the advantages and disadvantages of all-cause vs. cardiovascular-specific endpoints, *e.g.,* hospitalizations and deaths;
6. Discuss the advantages and disadvantages of adjudicating causes of deaths and hospitalizations.

## III. Participating in the Public Workshop

*Registration:* To register for the public workshop, please visit the following website *https://fdaheartfailureendpointsindrugdev.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public workshop must register by July 24, 2019, at 3 p.m., Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Meg Pease-Fye at 301–796–2240 no later than July 1, 2019.

*Requests for Oral Comment:* On the day of the meeting, a signup sheet will be made available for those who wish to speak during the public comment session. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their

comments. On the day of the meeting, based on demand, we will determine the amount of time allotted to each presenter and the approximate time each comment is to begin. Please note this will be oral comment only; no slides or other presentation material is permitted. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

*Streaming Webcast of the Public Workshop:* This public workshop will also be webcast via *https://collaboration.fda.gov/thf072519/.*

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.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at *https://www.fda.gov.*

Dated: June 24, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–13799 Filed 6–27–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–D–2314]**

### Treatment for Heart Failure: Endpoints for Drug Development; 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 ''Treatment for Heart Failure: Endpoints for Drug Development.'' This draft guidance clarifies that an effect on symptoms or physical function, without a favorable effect on survival or hospitalization, can be a basis for approving drugs to treat heart failure. It also provides recommendations to sponsors on the need to assess mortality effects of drugs under development to treat heart failure.

**DATES:** Submit either electronic or written comments on the draft guidance by August 27, 2019 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–2019–D–2314 for ''Treatment for Heart Failure: Endpoints for Drug Development.'' 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.

- 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.gpo.gov/fdsys/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.

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; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label