V. Attendance and/or Participation at the Public Meeting

A. Purpose and Scope of the Meeting

The purpose of this meeting and public docket is for CDER and CBER to hear from stakeholders any questions, concerns, and suggestions regarding the proposed plans for the scope and implementation of the quality metrics reporting program proposed in this guidance.

B. Questions to Stakeholders

FDA seeks input from stakeholders and other members of the public on the following meeting questions:

1. Are there other objective metrics that FDA should request in advance of or in lieu of an inspection that FDA should collect to improve our understanding of products and establishments for purposes of more informed, risk-based inspection scheduling and identification of potential product shortages?
2. Are the definitions of the metrics and associated data requests selected adequate and clear?
3. Are the metrics requested from each business segment/type clear and appropriate?
4. Should the Agency explore collecting metrics from high-risk excipient producers, and if so, which excipients should be considered high-risk and what metrics should apply?
5. Should the Agency explore collecting metrics from the medical gas manufacturing industry?
6. Should the Agency add the ''Right First Time'' metric (see section I.), and if so, should the definition be a rework/reprocessing rate or a measure of lots manufactured without processing deviations?
7. What data standards/mechanisms would be useful to aid reporting and how should the submissions be structured?
8. Are there reporting hurdles to collecting metrics by reporting establishment/product (segmented by site) versus by site (segmented by product), and how can they be overcome?
9. FDA may consider whether to require the submission of quality metrics on a recurring basis. How frequently should metrics be reported and/or segmented within the reporting period (*e.g.,* annually, semiannually, or quarterly)?

C. Meeting Participation and Request To Present

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by Web cast (see *Streaming Web Cast of the Public Meeting*)) and/or present at the meeting, please register for the meeting and/or make a request for oral presentations or comments by visiting *https://qualitymetrics-public-meeting.eventbrite.com* on or before August 7, 2015. The registration request should contain complete contact information for each attendee (*i.e.,* name, title, affiliation, address, email address, telephone number, and priority number(s)). Those without email access can register by contacting Althea Cuff by August 7, 2015 (see **FOR FURTHER INFORMATION CONTACT**).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the topic, or topics, they wish to address (see section V.B.). This will help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation to Althea Cuff at *Althea.Cuff@fda.hhs.gov* on or before August 7, 2015. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make a presentation.

Persons registered to make an oral presentation are encouraged to arrive at the meeting room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the meeting and other background materials will be made available 3 days before the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm*. If you need special accommodations because of a disability, please contact Althea Cuff (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Meeting Registration and Request to Present: The meeting is free and seating will be on a first-come, first-served basis. If you wish to attend or make an oral presentation, see section V.C. for information on how to register and the deadline for registration. If you cannot attend in person, information about how you can access a live Web cast will be located at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm*.

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may also be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Streaming Web Cast of the Public Meeting: For those unable to attend in person, FDA will provide a live Web cast of the meeting. To join the meeting via the Web cast, please go to *https://collaboration.fda.gov/qmpm2015/*. An agenda will be posted on the FDA Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm* prior to the meeting.

Docket Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document to the public docket (see **ADDRESSES**) by (see **DATES**). Given that time will be limited at the public meeting, FDA encourages all interested persons to comment in writing to ensure that their comments are considered.

VI. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*.

Dated: July 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18448 Filed 7–27–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Chronic Fatigue Syndrome Advisory Committee

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will be held on Tuesday, August 18, 2015, from 9:00 a.m. until 5:00 p.m., ET and Wednesday, August 19, 2015, from 9:00 a.m. until 5:00 p.m., ET.

ADDRESSES: Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 800, Washington, DC 20201. For a map and directions to the Hubert H. Humphrey building, please refer to *http://www.hhs.gov/about/hhh.html.*

FOR FURTHER INFORMATION CONTACT: Any questions about meeting registration or public comment sign-up should be directed to *CFSACmtg@hhs.gov.* Please direct other inquiries to *CFSAC@hhs.gov.*

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002 to advise, consult with, and make recommendations to the Secretary, through the Assistant Secretary for Health, on a broad range of topics including: (1) The current state of knowledge and research and the relevant gaps in knowledge and research about the epidemiology, etiologies, biomarkers, and risk factors relating to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), and identifying potential opportunities in these areas; (2) impact and implications of current and proposed diagnosis and treatment methods for ME/CFS; (3) development and implementation of programs to inform the public, health care professionals, and the biomedical research communities about ME/CFS advances; and (4) strategies to improve the quality of life of ME/CFS patients.

The agenda for this meeting is being developed and will be posted on the CFSAC Web site, *http://www.hhs.gov/advcomcfs/* when finalized. The meeting will be live-video streamed at *http://www.hhs.gov/live* and archived through the CFSAC Web site: *http://www.hhs.gov/advcomcfs/.* Listening-only via telephone will be available on both days. Call-in information will be posted on the CFSAC Web site.

Individuals who plan to attend in-person on one or both days will need to register in advance so that information can be provided to government security officials to facilitate entrance to the building. A registration form should be downloaded from the CFSAC Web site (*http://www.hhs.gov/advcomcfs/*), completed, and emailed to *CFSACmtg@hhs.gov* to facilitate entrance through building security. Registration will be open on July 27, 2015. All registration should be completed by August 13, 2015. Using the same process as above, members of the media will need to register at *CFSACmtg@hhs.gov.* All attendees will be required to show valid government-issued *picture* identification (state or federal) for entry into the federal building. Attendees will receive a wrist band that must be worn the entire time. Security requires all non-federal employees to be escorted the entire time they are in the building. Upon leaving the building for any reason, persons will be required to follow the security steps mentioned above and receive a new wrist band.

Attendance by visitors who are not U.S. citizens is welcome, but prior approval is required. A form for non-U.S. citizens can be downloaded from the CFSAC Web site (*http://www.hhs.gov/advcomcfs/*), completed, and emailed to *CFSACmtg@hhs.gov before* August 1, 2015.

Members of the public will have the opportunity to provide public comment at the meeting or via telephone. International calls cannot be accommodated. Individuals wishing to provide public comment in-person or via phone will be required to request time for public comment by Monday, August 10, 2015 at the following link: *CFSACmtg@hhs.gov.* An email will be sent by August 13, 2015 to confirm an individual's time for public comment. Each speaker will be limited to three minutes for public comment. No exceptions will be made. Priority will be given to individuals who have not provided public comment within the previous year.

You are not required to submit a written copy of your testimony unless you wish to have it included in the public record. Individuals wishing to submit written comment for the public record should send an electronic copy of their written testimony to: *CFSACmtg@hhs.gov* by August 13, 2015. The document for public record must not exceed 5 single-spaced, typed pages, using a 12-point typeface; it is preferred that the document be prepared in the MS Word format. Please note that PDF files, hand-written notes, charts, and photographs will not be posted on the CFSAC Web site.

Requests to participate in the public comment and provide written testimony will not be accepted at *CFSAC@hhs.gov.* Please send all questions about public comment requests or inquiries to *CFSACmtg@hhs.gov.*

Only written testimony submitted for public record and received by August 13, 2015 are part of the official meeting record; this testimony will be posted to the CFSAC Web site within 60 days after the meeting. Materials submitted should not include sensitive personal information, such as social security number, birthdates, driver's license number, state identification or foreign country equivalent, passport number, financial account number, credit or debit card number. If you wish to remain anonymous the document must specify this.

Persons who wish to distribute printed materials in person (at their own expense) to CFSAC members during the meeting should submit one copy for approval to the Designated Federal Officer at *CFSACmtg@hhs.gov,* prior to August 13, 2015.

Dated: July 17, 2015.

Nancy C. Lee,

Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. 2015–18444 Filed 7–27–15; 8:45 am]

BILLING CODE 4150–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues (the Commission) will conduct its twenty second meeting on September 2, 2015. At this meeting, the Commission will continue to discuss the role of deliberation and deliberative methods to engage the public and inform consideration in bioethics, and how to integrate pubic dialogue into the bioethics conversation; bioethics education as a forum for fostering deliberative skills, and preparing students to participate in public dialogue in bioethics; goals and methods of bioethics education; and integrating bioethics education across a range of professional disciplines and educational levels.

DATES: The meeting will take place on September 2, 2015, from 9 a.m. to approximately 5 p.m.

ADDRESSES: Renaissance Washington Hotel, 999 9th Street NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Lisa M. Lee, Executive Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Lisa.Lee@bioethics.gov.* Additional information may be obtained at *www.bioethics.gov.*