for Accelerated and Traditional Approval'' issued in October 2002.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 5, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6370, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment.'' This guidance revises the guidance for industry entitled ''Antiretroviral Drugs Using Plasma HIV–RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval'' issued in October 2002. Significant changes from the 2002 version include: (1) More details on nonclinical development of antiretroviral drugs; (2) a greater emphasis on recommended trial designs for HIV–1 infected heavily treatment-experienced patients (those with multiple-drug, resistant virus and few remaining therapeutic options); (3) use of a primary endpoint evaluating early virologic changes for studies in heavily treatment-experienced patients; and (4) use of the traditional approval pathway for initial approval of all antiretrovirals with primary analysis time points dependent on the indication sought instead of an accelerated approval pathway followed by traditional approval. Longer term trials may be appropriate for patients who are treatment-naïve or have limited prior experience, whereas shorter term trials may be appropriate for patients with limited treatment options.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing antiretroviral drugs for the treatment of HIV–1 infection. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014, the collections of information in 21 CFR part 314 have been approved under 0910–0001, and the collections of information referred to in the guidance for industry entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

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

Dated: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13288 Filed 6–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0580]

Battery-Powered Medical Devices Workshop: Challenges and Opportunities; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Battery-Powered Medical Devices Workshop: Challenges and Opportunities''. The purpose of this workshop is to create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices.

Date and Time: The public workshop will be held on July 30 and 31, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. All visiting public workshop participants (non-FDA employees) must enter through Building 1 for routine security check procedures. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Contact: Iacovos Kyprianou, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 3609, Silver Spring, MD 20993–0002, 301–796–2601, email: *iacovos.kyprianou@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m., July 19, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the workshop will be available beginning at 7 a.m.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://*

www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, and affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan, *susan.monahan@fda.hhs.gov* or 301–796–5661, to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (*susan.monahan@fda.hhs.gov* or 301–796–5661) no later than 5 p.m. on July 17, 2013.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m., July 19, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after July 24, 2013. If you have never attended an Adobe 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 *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This public workshop includes public comment and topic-focused sessions. If you wish to present, please so indicate at time of registration. Please indicate whether you wish to present during a public comment session, or participate in a specific session. Please submit the topic and a short abstract of your presentation. FDA will do its best to accommodate requests to make public comment and participate in specific 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 specific sessions. Following the close of registration, FDA 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 July 22, 2013. All requests to make oral presentations must be received by the close of registration at 5 p.m., July 19, 2013. If selected for presentation, any presentation materials must be emailed to Iacovos Kyprianou (see *Contact*) no later than July 24, 2013. No commercial promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain information on battery-powered medical devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop and the issues discussed during the meeting is August 30, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when commenting on specific topics as outlined in section II of this document, please identify the topics you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Batteries play a significant role in the overall safety, performance, and reliability of many life-saving and life-sustaining medical devices. As more medical devices become computerized, compact, and mobile, the number of battery-powered medical devices will continue to increase. While many different components can potentially impact the safety and effectiveness of medical devices, the battery can be one of the most critical components. Unexpected depletion or failure of the battery can cause the device to stop functioning properly, preventing the device from delivering life-sustaining or life-saving therapy. The Association for the Advancement of Medical Instrumentation has identified battery management as one of the top 10 challenges for hospitals' biomedical departments. In addition, the way that the battery is integrated into the overall device plays a critical role in the performance of the device. In many cases, the cause of the problem is identified as ''battery failure'' even when the battery is not the root cause of the problem. Improper charging of rechargeable batteries and inconsistent maintenance of batteries in general can adversely impact the effectiveness of the device, causing unexpected failure of devices at critical times, such as emergency situations where electrical power is unavailable or intermittent. While FDA has confidence that medical devices currently being marketed will continue to function as intended, there are opportunities to further improve their overall performance and safety. Therefore, FDA is organizing a Battery-Powered Medical Devices Workshop on July 30 and 31, 2013, to create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices. The forum will be held at the FDA's White Oak campus in Silver Spring, MD from 8 a.m. to 5 p.m. The participants would include a broad group of stakeholders that are responsible for the design, testing, manufacturing, integration, regulation, selection, purchase, storage, maintenance, and use of batteries throughout the total product life cycle of battery-powered medical devices.

II. Topics for Discussion

At this meeting, participants will engage in open dialogue and discuss the following factors that contribute to battery-powered medical device performance and reliability:

- Identification of challenges,
- Battery/device design and system integration,
- Battery/device manufacturing process,
- Battery/device maintenance,
- Human factors,
- Consistent labeling,
- User training,
- Special considerations under extreme conditions,
- Standardization,
- Emerging technology and innovation, and
- Mitigation of challenges.

Goals

1. Create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices.
2. Create a forum for open dialogue among stakeholders to share lessons learned and best practices for overcoming battery-powered medical device challenges.
3. Promote better design, manufacturing, testing, system integration, maintenance and standardization of battery-powered medical devices.
4. Understand the challenges of hospitals, health care providers, and patients in selection, purchase, use, and maintenance of battery-powered medical devices.
5. Promote innovation in technology and processes to improve device performance and reliability.
6. Coordinate future collaboration in the development of educational materials, standards, and guidance.

Dated: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13244 Filed 6–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0596]

Lung Cancer Patient-Focused Drug Development; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for lung cancer. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of lung cancer on daily life as well as the available therapies for lung cancer.

DATES: The public meeting will be held on June 28, 2013, from 8:30 a.m. to 12:30 p.m. Registration to attend the meeting must be received by June 19, 2013 (see **SUPPLEMENTARY INFORMATION** for instructions). Submit electronic or written comments by July 29, 2013.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security checks will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the complete agenda and additional meeting background material approximately 5 days before the meeting at *http://www.fda.gov/Forindustry/UserFees/PrescriptionDrugUserFee/ucm353273.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1199, Silver Spring, MD 20993, 301–796–0684, FAX: 301–847–8443, email: *graham.thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected lung cancer to be the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments made as part of the reauthorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (FDASIA) (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

FDA has committed to obtaining the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a document (78 FR 21613) in the **Federal Register** that announced the disease areas for meetings in fiscal years (FY) 2013 to 2015, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in the April 11, 2013, document to develop the list of disease areas. Public comment on the Agency's proposed criteria and potential disease areas was gathered through a **Federal Register** document for public comment that was published on September 24, 2012 (77 FR 58849), and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. By the end of FY 2015, FDA will initiate a public process for determining the disease areas for FY 2016 and 2017. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will gather patient and patient stakeholder input on symptoms of lung cancer that matter most to patients and on current approaches to treating lung cancer. Lung cancer is a disease caused by uncontrolled growth of abnormal cells in the tissues of the lung, usually in the cells lining air passages. Lung cancer cells can spread (metastasize) to almost