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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 5, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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, 301–796–2601, email: iacovos.kyprianou@fda.hhs.gov.

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FDA is announcing the availability of a draft guidance for industry entitled “Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment.”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 anyone 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 321 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.


Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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://
1. 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:

...
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.

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