

IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. The guidances, notices, and 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>.

V. 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: October 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-26546 Filed 11-5-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1021]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2014 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the Web site location where the Agency will post two lists of guidance documents the Center for Devices and Radiological Health (CDRH) is intending to publish in Fiscal Year (FY) 2014. In addition, FDA has established a docket where stakeholders may provide comments and/or propose draft language for those topics, suggest new or different guidance documents, and comment on the priority of topics for guidance.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: Submit electronic comments on the proposed 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: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993-0002, 301-796-5678.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of prioritized medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the "A-list") and a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the "B-list"). In addition to posting lists of prioritized device guidance documents, FDA has committed to updating its Web site in a timely manner to reflect the Agency's review of previously published guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency. Fulfillment of this commitment will be reflected through the issuance of updated guidance on existing topics, removal of guidances that no longer reflect FDA's current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

This notice announces the Web site location of the two lists of guidance documents which CDRH is intending to publish during FY 2014. We note that the Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. The Agency is not precluded from issuing guidance documents that are not on either list.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. CDRH's experience in

guidance development has shown that there are many reasons that CDRH staff may not complete the entire agenda of guidances it undertakes. Staffs are frequently diverted from guidance development to other priority activities. In addition, at any time new issues may arise to be addressed in guidance that could not have been anticipated at the time the annual list is generated. These may involve newly identified public health issues.

FDA anticipates that feedback from stakeholders, including draft language for guidance documents, will allow CDRH to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the lists. FDA has established a docket where comments on the FY 2014 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual Agency-wide notice issued under its good guidance practices (21 CFR 10.115(f)(5)). The CDRH lists, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site at the beginning of each FY from 2013 to 2017. To access the lists of guidance documents CDRH is intending to publish in FY 2014, visit FDA's Web site <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm>.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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>.

Dated: October 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-N-2013-1328]

Sickle Cell Disease Public Meeting on Patient-Focused Drug Development

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 sickle cell disease. Patient-Focused Drug Development is part of FDA's performance commitments in 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 sickle cell disease on daily life and on available therapies for sickle cell disease.

DATES: The public meeting will be held on February 7, 2014; from 10 a.m. to 4 p.m. Registration to attend the meeting must be received by January 27, 2014. See the SUPPLEMENTARY INFORMATION section for information on how to register for the meeting. Submit electronic or written comments by April 8, 2014.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, in Sections B and C of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, 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 agenda approximately 5 days before the meeting at: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm370867.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, 301-796-5003, Fax: 301-847-8443, email: Graham.Thompson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected sickle cell disease to be the focus of a 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's performance commitments made as part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (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 obtain 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 available therapies for sickle cell disease. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice (78 FR 21613) in the **Federal Register** announcing the disease areas for meetings in fiscal years (FYs) 2013 through 2015, the first 3 years of the 5-year PDUFA V timeframe. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 2013 notice. The Agency obtained public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 58849), and through a public meeting held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the

perspectives of its review divisions. By the end of FY 2015, FDA will initiate another public process for determining the disease areas for FYs 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 obtain patient and patient stakeholder input on sickle cell disease and on current approaches to treatment. Approximately 100,000 people in the United States, and millions of people worldwide, have sickle cell disease. Sickle cell disease is an inherited red blood cell disorder resulting from a mutation in the beta globin gene. Red blood cells are more prone to an abnormal shape and rigidity, causing multi-organ damage over time. Some of the effects of sickle cell disease are painful crises, increased risk of infections, stroke, pulmonary hypertension, acute chest syndrome, recurrent priapism, gallstones, and kidney dysfunction.

Therapies to prevent the complications of sickle cell disease are limited and can include prescription medications and blood transfusions. Bone marrow transplantation is an option for some patients. Other therapies, such as pain medications, antibiotics, supplemental oxygen, and vitamin supplements, are used to manage specific health effects of the disease. New approaches to treating sickle cell disease or preventing its complications are being explored, including new medications, advances in transplantation, and gene therapies. FDA is interested in obtaining a better understanding of patients' perspectives on sickle cell disease, including the symptoms that matter most to patients, limitations to current treatment approaches, opportunities for new treatment approaches, and specific considerations regarding sickle cell disease in pediatric patients.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions