thinking on drug product naming nomenclature for new drugs that contain a salt as the active ingredient. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this guidance that are related to the burden for the submission of investigational new drug applications are covered under 21 CFR 312 and have been approved under OMB control number 0910–0014. The collections of information referenced in this guidance that are related to the burden for the submission of new drug applications that are covered under 21 CFR 314 have been approved under OMB control number 0910–0001. The submission of prescription drug product labeling under 21 CFR 201.56 and 201.57 is approved under OMB control number 0910–0572.

The guidance also references 21 CFR 201.10 ''Drugs; Statement of Ingredients.'' In the **Federal Register** of December 18, 2014 (79 FR 75506), FDA published its proposed rule on the electronic distribution of prescribing information for human prescription drugs, including biological products. In Section VII, ''Paperwork Reduction Act of 1995,'' FDA estimated the burden to design, test, and produce the label for a drug product's immediate container and outer container or package, as set forth in 21 CFR part 201, including §§ 201.10, 201.100(b), and other sections in subpart A and subpart B.

## III. 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.*

## 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: June 10, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–14884 Filed 6–16–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–D–1242]**

### Content and Format of Abbreviated 510(k)s for Early Growth Response 1 Gene Fluorescence In-Situ Hybridization Test System for Specimen Characterization Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices.'' This guidance provides industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for EGR1 gene FISH test system for specimen characterization devices.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Shyam Kalavar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5568, Silver Spring, MD 20993–0002, 301–796–6807.

**SUPPLEMENTARY INFORMATION:**

## I. Background

This guidance document was developed to provide industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for EGR1 gene FISH test system for specimen characterization devices and recommendations for addressing certain labeling issues relevant to the review process specific to these devices. An EGR1 gene FISH test system for specimen characterization is a device intended to detect the EGR1 probe target on chromosome 5q in bone marrow specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted only by a qualified pathologist or cytogeneticist. These devices do not include automated systems that directly report results without review and interpretation by a qualified pathologist or cytogeneticist. These devices also do not include any device intended for use to select patient therapy, predict patient response to therapy, or to screen for disease as well as any device with a claim for a particular diagnosis, prognosis, and monitoring or risk assessment.

In the **Federal Register** of September 26, 2014 (79 FR 57939), the Agency issued the draft guidance entitled ''Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices.'' The Agency received no comments on the draft guidance dated September 26, 2014.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Content and

Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. 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.*

**IV. Paperwork Reduction Act of 1995**

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, are currently approved under OMB control number 0910–0120 and the collections of information in 21 CFR 809.10 are currently approved under 0910–0485.

**V. 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: June 12, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–14881 Filed 6–16–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0389]**

### Medical Device User Fee Amendments; Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting on the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years 2018 through 2022. The current legislative authority for the medical device user fee program expires on October 1, 2017, and new legislation will be required for FDA to continue collecting user fees for the medical device program in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that before FDA begins negotiations with the regulated industry on MDUFA reauthorization, we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting at which the public may present its views on the reauthorization, provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to MDUFA, and publish the comments on FDA's Web site. FDA invites public comment on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program.

*Date and Time:* The public meeting will be held on July 13, 2015, from 9 a.m. to 5 p.m.

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

*Contact Person:* Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5449, Silver Spring, MD 20993, 301–796–5178, email: *Aaron.Josephson@fda.hhs.gov.*

*Registration:* Registration is required to attend this meeting in person or to view the Webcast. Registration is free and available on a first-come, first-served basis. Persons interested in participating in the meeting must register online by July 2, 2015, at 4 p.m. Early registration is recommended because space is 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 meeting will be provided beginning at 8 a.m.

If you have registered and need special accommodations, please contact Susan Monahan, 301–796–5661, email: *Susan.Monahan@fda.hhs.gov,* no later than July 1, 2015.

To register for the public meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register. All registrants will receive confirmation after they have been successfully registered. Registrants not confirmed to participate, but added to a waiting list, will be notified of that as well.

*Streaming Webcast of the Public Meeting:* This public meeting will be Webcast. Persons interested in viewing the Webcast must register online (see Web link above) by July 2, 2015, at 4 p.m. Early registration is recommended because Webcast connections are limited. FDA requests that organizations with multiple registrants in the same location register all participants individually but view the Webcast using one connection per location. Webcast participants will be sent technical system requirements upon confirmation and will be sent connection access information after July 6, 2015. If you have not previously attended an event hosted by Connect Pro, it is recommended that you test your connection in advance at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* A short overview of the Connect Pro program is available at *http://www.adobe.com/go/connectpro_overview.*

*Requests for Oral Presentations:* This public meeting includes public comment and topic-focused sessions. During registration you may indicate if you wish to present during a public comment session or participate in a topic-focused session, and specify the topic(s) you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate all persons who wish to speak. FDA encourages individuals and organizations with common interests to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the topic-focused sessions. After