

any requests for designation. Thus, FDA estimates that one or fewer will be received annually in the future. Based on this experience, FDA estimates the annual number of new requests for designation will be one. FDA estimates that preparing the information required by §§ 189.5 and 700.27 and submitting it to FDA in the form of a written request to the CFSAN Director will require a burden of approximately 80 hours per request. Thus, the burden for new requests for designation is estimated to be 80 hours annually, as shown in table 1, row 1 of this document.

Under §§ 189.5(e) and 700.27(e), designated countries are subject to future review by FDA and may respond to periodic FDA requests by submitting information to confirm their designations remain appropriate. In the last 3 years, FDA has not requested any reviews. Thus, FDA estimates that one or fewer will occur annually in the future. FDA estimates that the designated country undergoing a review in the future will need one-third of the time it took preparing its request for designation to respond to FDA's request for review, or 26 hours (80 hours multiplied by 0.33 (2 minutes) = 26.4 hours, rounded to 26). The annual burden for reviews is estimated to be 26 hours, as shown in table 1, row 2 of this document. The total annual reporting burden for this information collection is estimated to be 1,915 hours.

#### *Recordkeeping*

FDA estimates that there are 697 domestic facility relationships and 916 foreign facility relationships consisting of the following facilities: An input supplier of cattle-derived materials that requires records (the upstream facility) and a purchaser of cattle-derived materials requiring documentation (this may be a human food or cosmetics manufacturer or processor). The recordkeeping burden of FDA's regulations in §§ 189.5(c) and 700.27(c) is the burden of sending, verifying, and storing documents regarding shipments of cattle material that is to be used in human food and cosmetics.

In this estimate of the recordkeeping burden, FDA treats these recordkeeping activities as shared activities between the upstream and downstream facilities. It is in the best interests of both facilities in the relationship to share the burden necessary to comply with the regulations; therefore, FDA estimates the time burden of developing these records as a joint task between the two facilities. Thus, FDA estimates that this recordkeeping burden will be about 15 minutes per week or 13 hours per year,

and FDA assumes that the recordkeeping burden will be shared between 2 entities (i.e. the ingredient supplier and the manufacturer of finished products). Therefore, the total recordkeeping burden for domestic facilities is estimated to be 9,061 hours (13 hours multiplied by 697), and the total recordkeeping burden for foreign facilities is estimated to be 11,908 hours (13 hours multiplied by 916), as shown in table 1 of this document.

Dated: September 22, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2014-D-1242]**

#### **Submissions for Early Growth Response 1 Gene Fluorescence In-Situ Hybridization Test System for Specimen Characterization Devices; Draft 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 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." This draft guidance provides industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization devices. This draft guidance is not final nor is it in effect at this time.

**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 December 26, 2014.

**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 draft 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 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. 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 draft 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 early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization devices and recommendations for addressing certain labeling issues relevant to the review process specific to these devices. An early growth response 1 (EGR1) gene fluorescence in-situ hybridization (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.

## II. Significance of Guidance

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 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 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 statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "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" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1400030 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft 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 part 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: September 22, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–22973 Filed 9–25–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2006–D–0031]

#### Draft Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Reopening of the Comment Period

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

**ACTION:** Notice; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance document entitled "Informed Consent Information Sheet." A notice of availability requesting comments on the draft guidance document appeared in the *Federal Register* of July 15, 2014. The Agency is reopening the comment period to update comments and to receive any new information.

**DATES:** Submit either electronic or written comments by October 27, 2014.

**ADDRESSES:** 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.

**FOR FURTHER INFORMATION CONTACT:** Marsha Melvin, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Building 32, Silver Spring, MD 20993, [marsha.melvin@fda.hhs.gov](mailto:marsha.melvin@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

In the *Federal Register* of July 15, 2014 (79 FR 41291), FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance document entitled "Informed Consent Information Sheet."

The Agency has received a request for a 30-day extension of the comment period for the draft guidance. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance.

FDA is reopening the comment period for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance on these important issues.

## 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: September 19, 2014

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA–2014–M–0327, FDA–2014–M–0434, FDA–2014–M–0552, FDA–2014–M–0553, FDA–2014–M–0690; FDA–2014–M–0691, FDA–2014–M–0692, FDA–2014–M–0726, FDA–2014–M–0727, FDA–2014–M–0866, and FDA–2014–M–0872]

#### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and