



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for Early Growth Response 1 Gene Fluorescence In-Situ Hybridization Test System for Specimen Characterization Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen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 This draft guidance provides industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for early growth response 1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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 Submit written requests for a single hard copy of the draft guidance document entitled "Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for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Submit electronic comments on the draft guidance to 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 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.

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