

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.

Dated: November 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0565]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Clostridium difficile*; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled “Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Clostridium difficile*.” This draft guidance document describes FDA’s recommendations concerning 510(k) submissions for various types of in vitro diagnostic devices (IVDs) intended to be used for detecting *Clostridium difficile* (*C. difficile*). This draft guidance is not final nor is it in effect at this time.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on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 28, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Clostridium difficile*” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. *See* the **SUPPLEMENTARY**

INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, 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:

Stephen Lovell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4435, Silver Spring, MD 20993-0002, 301-796-6968.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance includes recommendations concerning 510(k) submissions for various types of (IVDs) intended to be used for detecting *C. difficile*. The document is a revision of “Review Criteria for Assessment of Laboratory Tests Directed at Assisting in the Diagnosis of *C. difficile* Associated Disease” issued on May 31, 1990. It is updated to include new issues and technologies identified since the 1990 guidance. Such methods include detection of *C. difficile* nucleic acids (*e.g.*, *C. difficile* toxin B gene by nucleic acid amplification methods such as the Real-Time Polymerase Chain Reaction technique).

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 establishing the performance characteristics of in vitro diagnostic devices for the detection of *C. difficile*. 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 using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Clostridium*

difficile,” you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1715 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 42 CFR section 493.15 have been approved under OMB control number 0910-0598; the collections of information in 21 CFR section 50.23 have been approved under OMB control number 0910-0586; and the collections of information in 21 CFR section 56.115 have been approved under OMB control number 0910-0130.

V. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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