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<NOTICE>

<PREAMB>

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0179]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens." This document was developed to support the reclassification of nucleic acid-based in vitro diagnostic devices for the detection of M. tuberculosis complex in respiratory specimens from class III into class II. These devices are intended to be used as an aid in the diagnosis of pulmonary tuberculosis. This draft guidance document describes a means by which in vitro diagnostic devices for the detection of M. tuberculosis complex in respiratory specimens may comply with the requirement of special controls for class II devices.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens" 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Submit electronic comments on the draft guidance to 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 (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:

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## SUPPLEMENTARY INFORMATION:

### I. Background

Elsewhere in this issue of the Federal Register, FDA is publishing a proposed rule to reclassify nucleic acid-based in vitro diagnostic devices for the detection of M. tuberculosis complex in respiratory specimens into class II (special controls) from class III. Nucleic acid-based in vitro diagnostic devices for the detection of M. tuberculosis complex in respiratory specimens are qualitative nucleic acid-based in vitro diagnostic devices intended to detect M. tuberculosis complex nucleic acids extracted from human respiratory specimens. These devices are non-multiplexed and intended to be used as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. These devices do not include devices intended to detect the presence of organism mutations associated with drug resistance. Respiratory specimens may include sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavage or bronchial aspirate), or tracheal aspirates.

This draft guidance document identifies the proposed classification regulation, the product code, and identifies issues of safety and effectiveness that require special controls. FDA believes that the special controls described in the draft guidance when combined with the general controls will be sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

### II. Significance of Guidance

FDA believes that adherence to the recommendations described in this guidance document, when finalized, in addition to the general controls, will provide reasonable assurance

of the safety and effectiveness of nucleic acid-based in vitro diagnostic devices for the detection of M. tuberculosis complex in respiratory specimens classified under § 866.3372 (21 CFR 866.3372). If classified as a class II device under § 866.3372, nucleic acid-based in vitro diagnostic devices for the detection of M. tuberculosis complex in respiratory specimens will need to comply with the requirement for special controls; manufacturers will need to address the issues requiring special controls as identified in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

### 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 "Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens," you may either send an email request to [dsmica@fda.hhs.gov](mailto: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 1788 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. 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 56.115 have been approved under OMB control number 0910-0130; 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 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485.

#### 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. 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: March 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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