DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0730]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Yersinia Species Detection; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for *Yersinia* Species Detection.'' This draft guidance document describes a means by which in vitro diagnostic devices for *Yersinia* species (spp.) detection may comply with the requirement of special controls for class II 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 This draft guidance is not final nor is it in effect at this time.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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 6, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for *Yersinia* spp. Detection'' 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Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane rm.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: Beena Puri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5553, Silver Spring, MD 20993–0002, (301) 796–6202.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify in vitro diagnostic devices for *Yersinia* spp. detection into class II (special controls). This draft special controls guidance document was developed to support the proposed classification of in vitro diagnostic devices for *Yersinia* spp. detection, a previously unclassified preamendments device, into class II (special controls). On March 7, 2002, the Microbiology Devices Advisory Panel (the panel) recommended that in vitro diagnostic devices for *Yersinia* spp. detection be classified into class II. The panel believed that class II with the special controls (guidance document and limitations on the distribution) would provide reasonable assurance of the safety and effectiveness of the device. After the panel meeting, FDA found one additional in vitro diagnostic device for *Yersinia* spp. detection to be substantially equivalent to another device within that type. This device has the same intended use as its predicate device but makes use of newer nucleic acid amplification technology (NAAT). While the NAAT detection devices exhibit technological differences from the preamendments *Yersinia* spp. detection devices, FDA has determined that they are as safe and effective as, and do not raise different questions of safety and effectiveness than, their predicates. (See section 513(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(i)).)

This draft guidance document identifies the proposed classification regulation, the product code, identifies issues of safety and effectiveness that require special controls, and proposes distribution limitations. 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

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 in vitro diagnostic devices for *Yersinia* spp. detection. 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 ''Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for *Yersinia* spp. Detection,'' you may either send an email 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 1714 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 (the PRA) (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, and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

The labeling requirement listed in sections 5 and 8; Intended Use, is not subject to review under the PRA because it is a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2) and 21 CFR 1040.10(g)).

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 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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