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.

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Draft Guidance for Industry and Food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availability of the draft guidance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 This draft
guidance document describes FDA’s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 This draft guidance is not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
cconsiders your comment on this draft
guidance before it begins work on the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draft guidance by February 28, 2011.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single copies of the draft guidance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draft guidance to http://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)
tended 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

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
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 0910–0578; 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.