communicable diseases from one State to another State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety. Through these regulations, FDA is implementing its authority under section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)).

In the **Federal Register** of July 14, 2010 (75 FR 40839), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
120.6(c) and 120.12(a)(1) and (b)	1,875	365	684,375	0.1	68,437.5
120.7; 120.10(a); and 120.12(a)(2), (b), and (c)	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) and 120.12(a)(4)(ii) and (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d)	308	1	308	4	1,232
Total					358,466

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 of this document provides a breakdown of the total estimated annual recordkeeping burden. FDA bases this hour burden estimate on its experience with the application of HACCP principles in food processing.

The burden estimates in table 1 of this document are based on an estimate of the total number of juice manufacturing plants (i.e., 2,300) affected by the regulations. Included in this total are 850 plants currently identified in FDA's official establishment inventory plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers. The total burden hours are derived by estimating the number of plants affected by each portion of the final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the Agency's final regulatory impact analysis prepared for these regulations.

Moreover, these estimates assume that every processor will prepare sanitary standard operating procedures and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under the regulations.

Dated: September 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23824 Filed 9–22–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0459]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Helicobacter pylori*; 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 "Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Helicobacter pylori*." This draft guidance document provides industry and agency staff with updated recommendations concerning 510(k) submissions for various types of *in vitro* diagnostic devices (IVDs) intended to be used for detecting *Helicobacter pylori* (*H. pylori*). 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 of 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 December 22, 2010.

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 *Helicobacter pylori*" 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: Freddie M. Poole, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5520, Silver Spring, MD 20993–0002, 301–796–5457.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document provides recommendations on developing studies for establishing the performance characteristics of *in vitro* diagnostic devices for the direct or indirect detection of *H. pylori* bacteria in human blood, serum, urine, stool, or breath specimens. FDA believes these recommended studies will be relevant for premarket notification (510(k)) submissions for these device types. Detection methods listed in this guidance include blood and urine antibody tests, stool antigen test, carbon-13 (^{13}C) urea breath and blood tests, and the urease test. This draft guidance has been updated since the 1992 guidance document entitled "Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to *Helicobacter pylori*," to suggest information that submitters provide that is more appropriate given changes in understanding of the science of detection of *H. pylori* and to include technologies outside the scope of the old guidance, such as *H. pylori* urea breath tests and *H. pylori* antigen detection tests.

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 *H. pylori*. 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. To receive "Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Helicobacter pylori*" 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 1712 to identify the draft guidance you are requesting. 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*.

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 812 have been approved under OMB control number 0910–0078; 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 42 CFR 493.17 have been approved under OMB control number 0910–0607; and the collections of information in 21 CFR 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: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23644 Filed 9–22–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Ethical, Legal, and Social Research.

Date: September 27, 2010.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Richard A. Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 16, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–23849 Filed 9–22–10; 8:45 am]

BILLING CODE 4140–01–P