We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting emergency approval under 5 CFR 1320.13(a)(2)(iii), as we believe that the use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed for annual reports to Congress as required under sections 5001 and 5004 of the Recovery Act.

1. Type of Information Collection Request: New collection; *Title of Information Collection:* Recovery Act—Reporting Requirements for States Under FMAP Increase and TMA Provisions; *Use:* The American Recovery and Reinvestment Act of 2009 (Recovery Act), Public Law 111–5, requires that States submit quarterly reports to the Secretary of Health and Human Services in accordance with section 5001 Temporary Increase of Medicaid Federal Medical Assistance Percentage (FMAP) and section 5004(d) Extension of Transitional Medical Assistance (TMA). The reports under section 5001 are required for the period of October 1, 2008–September 30, 2011. The reports under section 5004 are required beginning on July 1, 2009 until the Federal authority for TMA coverage sunsets (now scheduled to sunset on December 31, 2010). Each State Medicaid agency will submit its quarterly reports to the appropriate Regional Office of CMS. The reports will be compiled and summarized for annual reports to Congress. *Form Number:* CMS–10295 (OMB#: 0938–New); *Frequency:* Reporting—Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 200; *Total Annual Hours:* 600. (For policy questions regarding this collection contact Richard Strauss at 410–786–2019. For all other issues call 410–786–1326.)

CMS is requesting OMB review and approval of this collection by *October 5, 2009,* with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by the noted deadline below.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by October 9, 2009:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number (CMS–10295), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

and,

OMB Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503. *Fax Number:* (202) 395–6974.

Dated: August 31, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–21674 Filed 9–8–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0386]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; 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 or Detection and Differentiation of Human Papillomaviruses.'' FDA is issuing this draft guidance to inform industry and agency staff of its recommendations for analytical and clinical performance studies to support premarket submissions for in vitro diagnostic devices intended for the detection or detection and differentiation of human papillomaviruses.

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 December 8, 2009.

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 or Detection and Differentiation of Human Papillomaviruses'' 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. 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 written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kate Simon, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5552, Silver Spring, MD 20993, 301–796–6204.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document recommends studies that may be used to establish the analytical and clinical performance of in vitro diagnostic devices (IVDs) for the detection or detection and differentiation of human papillomaviruses (HPV) in cervical specimens. This guidance is limited to studies intended to establish the performance characteristics of in vitro diagnostic HPV devices that are used in conjunction with cervical cytology for cervical cancer screening. It does not

address HPV devices that are intended to be used independent of a cervical cytology result.

The one product code established for this HPV DNA detection device is code MAQ, class III. The recommendations in this guidance apply to HPV diagnostic devices that detect HPV nucleic acid (not only HPV DNA, but HPV RNA, as well). Many of the recommendations will also apply to HPV detection devices that utilize targets other than HPV nucleic acid (such as HPV protein). This guidance therefore may encompass future HPV product codes beyond the one listed. Because HPV diagnostic devices are postamendment devices, they are automatically classified as class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

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 or detection and differentiation of human papillomaviruses. 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 or Detection and Differentiation of Human Papillomaviruses,'' 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 1699 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. 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 814 have been approved under OMB Control No. 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910–0078; and the collections of information in 21 CFR 809.10 have been approved under OMB Control No. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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: August 26, 2009.

Catherine M. Cook,

Associate Director for Regulations and Policy.

[FR Doc. E9–21725 Filed 9–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0260]

Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007.'' The document provides guidance to the industry in complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Defense, Communication and Emergency Response (HFS–005), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 1–888–SAFEFOOD.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2009 (74 FR 27803), FDA announced the availability of a draft guidance entitled ''Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007'' and gave interested parties an opportunity to submit comments by July 27, 2009. The agency reviewed and evaluated these comments and has modified the guidance where appropriate.

The guidance contains questions and answers intended to assist those parties responsible for complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (Public Law 110–085), including: (1) How, when, and where to submit reports to FDA; (2) who is required to submit reports to FDA; (3) what is required to be submitted to FDA; and (4) what may be required when providing notifications to other persons in the supply chain of an article of food.