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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 this guidance were approved under OMB Control Nos. 0910–0643 and 0910–0645. This guidance also refers to previously approved collections of information found in FDA regulations. The collection of information in 21 CFR 7.46 has been approved under OMB Control No. 0910–0249.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm* or *http://www.regulations.gov*.

Dated: September 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21713 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–N–0664]

Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of August 25, 2009 (74 FR 42907). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6793, FAX: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 25, 2009, FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on October 6, 2009. On page 42907, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committee will discuss new drug application (NDA) 021–825, with the proposed trade name FERRIPROX (deferiprone) film-coated tablets, manufactured by ApoPharma Inc. This product is an iron chelating agent, which is a drug that binds with iron in the body and helps to make elimination of iron easier, reducing iron build-up. There are two specific proposed indications (uses) of FERRIPROX: (1) For the treatment of iron overload, or build-up in patients with transfusion-dependent thalassemia, an inherited blood disorder that necessitates frequent transfusion of normal blood which can lead to iron build-up due to the iron content in the blood a patient receives; and (2) for the treatment of iron overload in patients with other transfusion-dependent anemias (other blood disorders that require frequent transfusions) for whom the use of other iron chelating agents has been considered inappropriate.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 2, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21556 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–N–0664]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 9, 2009, from 8:30 a.m. to approximately 4:30 p.m.

Location: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD.

Contact Person: Gail Dapolito or Danielle Cubbage, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20853, 301–827–1289, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On October 9, 2009, in open session, the Committee will discuss ISOLAGEN THERAPY, BLA 125348, Isolagen Technologies, Inc., for moderate to severe nasolabial fold wrinkles. Nasolabial fold wrinkles are the two skin folds that run from each side of the nose to the corners of the mouth.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee