4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0386]

Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; Draft Guidance for Industry and Food and Drug Administration Staff: Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human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." This draft guidance provides recommendations to facilitate study designs to establish the performance characteristics of in vitro diagnostic devices (IVDs) intended for the detection, or detection and differentiation, of human papillomaviruses (HPVs). This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human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 Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Natalia Comella, Center for Devices and Radiological Health, Food and Drug Administration, New Hampshire Ave., Bldg. 66, rm. 4536, Silver Spring, MD 20993-0002, 301-796-6226, Natalia.Comella@fda.hhs.gov, or Marina V. Kondratovich, Center for Devices and Radiological Health, Food and Drug Administration, New Hampshire Ave., Bldg. 66, rm. 4672, Silver Spring, MD 20993-0002, 301-796-6036, Marina.Kondratovich@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides recommendations to facilitate study designs to establish the performance characteristics of IVDs intended for the detection, or detection and differentiation,

of HPVs. These devices are used either in conjunction with cervical cytology to aid in screening for cervical cancer or as first-line primary cervical cancer screening devices. These devices include those that detect a group of HPV genotypes, particularly high risk HPVs, as well as devices that detect more than one genotype of HPV and further differentiate among them to indicate which genotype of HPV is present or which genotypes of HPV are present.

When finalized, this draft guidance is expected to provide detailed information on the types of studies the FDA recommends to support a premarket application for these devices. This draft guidance specifically addresses devices that qualitatively detect HPV nucleic acid from cervical specimens, but many of the recommendations will also be applicable to devices that detect HPV proteins. The draft 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 cancer screening or as first-line primary cervical cancer screening devices. This draft guidance does not address HPV testing from non-cervical specimens such as pharyngeal, vaginal, penile, or anal specimens, or testing for susceptibility to HPV infection. It does not address quantitative or semi-quantitative assays for HPV.

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 current thinking of FDA on evaluating the performance characteristics of IVDs intended for the detection, or detection and differentiation, of HPVs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it 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 downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1740 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 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; 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 parts 801 and 809 have been approved under OMB control number 0910-0485; and the collections of information in the guidance document entitled "Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable" have been approved under OMB control number 0910-0582.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at http://www.regulations.gov.

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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