detection, or detection and differentiation, of human papillomaviruses.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 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 20993–0002. 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 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: Kate Simon, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5552, Silver Spring, MD 20993–0002, (301) 796–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to provide industry and Agency staff with recommendations for studies to establish the performance characteristics of IVDs intended for the detection, or detection and differentiation, of human papillomaviruses. These devices are used in conjunction with cervical cytology to aid in screening for cervical cancer. They include devices that detect a group of human papillomavirus (HPV) genotypes, particularly high risk human papillomaviruses, as well as devices that detect more than one genotype of HPV and further differentiate among them to indicate which genotype(s) of HPV is (are) present.

In the **Federal Register** of September 9, 2009 (74 FR 46433), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by December 8, 2009. Five comments were received on the guidance document. We reviewed the comments and took their suggestions into consideration in revising this guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 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 or Detection and Differentiation of Human Papillomaviruses,'' 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 1740 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

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, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30552 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0086 (formerly Docket No. 2005D–0223)]

Guidance for Industry on Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals.'' The purpose of this guidance is to provide recommendations to industry for designing nonclinical toxicity studies to determine potential late radiation effects (radiation-induced injuries occurring after a latency period of several months to years) of therapeutic radiopharmaceuticals administered systemically. The purpose of such studies is to help minimize the risk of late-occurring irreversible radiation toxicities in clinical trials of therapeutic radiopharmaceuticals. This guidance finalizes the draft guidance of the same name issued in June 2005.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the 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.

FOR FURTHER INFORMATION CONTACT: Adebayo Laniyonu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2350, Silver Spring, MD 20993–0002, (301) 796–2050; or Siham Biade, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2311, Silver Spring, MD 20993–0002, (301) 796–2050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals.'' The objective of this guidance is to provide recommendations to industry for designing nonclinical toxicity studies to determine potential late radiation effects of therapeutic radiopharmaceutical agents. This guidance is not intended to address late radiation toxicity of radiobiologicals (e.g., radiolabeled monoclonal antibodies) or to apply to diagnostic radiopharmaceuticals whose low doses are not expected to elicit late radiation toxic effects.

This guidance focuses solely on late radiation safety concerns that are unique to therapeutic radiopharmaceuticals and provides recommendations for late radiation toxicity nonclinical study designs including issues regarding good laboratory practices, species selection, dose selection, timing of study, and study parameters.

Late radiation toxicity differs from early or acute radiation toxicity. Acute radiation toxicity (*e.g.,* bone marrow failure, nausea, vomiting, diarrhea, and oral mucositis) occurs within days to weeks of an acute dose of radiation and is often self-limiting and reversible. In contrast, late radiation toxicity (*e.g.,* renal failure, pulmonary fibrosis, and chord transection) occurs after a latency period of several months to years during which relatively normal organ function continues. Late radiation toxicity is usually progressive and irreversible.

Therapeutic radiopharmaceuticals are typically administered systemically to treat cancer. The radiation absorbed doses delivered by therapeutic radiopharmaceuticals may be comparable to those delivered with external beam radiotherapy (XRT). At therapeutic doses of radiation, the late radiation toxicities commonly associated with XRT (*e.g.,* brain necrosis, paralysis, pulmonary fibrosis, liver or kidney failure, and hemorrhagic cystitis) can also be seen with therapeutic radiopharmaceuticals. With XRT, if the total dose given to an organ is less than its tolerance dose, the probability of symptomatic late radiation toxicity to that organ (exclusive of estimated risks of secondary malignancy) will be minimal. The tolerance doses of most human organs for conventional fractionated XRT are known, and are routinely used to direct the safe administration of XRT. In FDA's experience, however, there are few clinical data from which to estimate organ tolerance doses for therapeutic radiopharmaceuticals. Furthermore, late radiation toxicity has been observed when estimates of radiation absorbed doses delivered by therapeutic radiopharmaceuticals to target organs were substantially below the published XRT organ tolerance doses.

Therefore, there is a need to gain additional knowledge in this area to support the safe administration of therapeutic radiopharmaceuticals to humans. Because studies in humans would be unethical, the best means to gain insight into this issue is by conducting nonclinical late radiation toxicity studies. These studies will aid in identifying organs at risk and establish a margin of safety for late radiation toxicity. As a result, these studies will help to minimize the risk of late-occurring radiation toxicities in clinical trials of therapeutic radiopharmaceuticals.

This guidance finalizes the draft guidance of the same name issued in June 2005 and includes edits based on public comments to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on nonclinical evaluation of late radiation toxicity of therapeutic radiopharmaceuticals. 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 statutes and regulations.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30474 Filed 11–25–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No: FDA–2011–N–0002]

Science Board to the Food and Drug Administration; 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: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues, as well as emerging issues within the scientific community in industry and academia. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.