

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.

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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.

Date and Time: The meeting will be held on January 6, 2012, from 9 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at <https://collaboration.fda.gov/scienceboard/>. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Martha Monser, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 32, rm. 4286, Silver Spring MD 20993-0002, (301) 796-4627, or FDA Advisory Committee Information Line, 1-(800) 741-8138 (301) 443-0572 in the Washington, DC area), and follow the prompt to the desired center or product area. 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: The Science Board will hear about and provide input regarding the two Centers for Excellence in Regulatory Science and Innovation. The Science Board will also hear updates regarding the Scientific Computing/JANUS program, and FDA's Scientific Integrity Policy. FDA's Modernizing Toxicology Working Group will present an overview to the Science Board for input and discussion. The Center for Drug Evaluation and Research (CDER) will provide their response to the May 2011 Subcommittee Report regarding the Review of the FDA/CDER Pharmacovigilance Program.

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 meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 22, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 23, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Ms. Martha Monser, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 18, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-30416 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]

Request for Nominations for Voting Members on Public Advisory Committee, Science Board to the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Science Board to the FDA (the Science Board).

FDA has special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations received on or before December 28, 2011, will be given first consideration for membership on the Science Board. Nominations received after December 28, 2011, will be considered for nomination to the Science Board should nominees still be needed.

ADDRESSES: All nominations for membership should be sent electronically to CV@FDA.HHS.GOV, or by mail to Advisory Committee Oversight & Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is: Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4286, Silver Spring, MD 20993-0002, (301) 796-4627, email: martha.monser@fda.hhs.gov.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: <http://www.fda.gov/oc/advisory/default.htm>.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Science Board.

I. General Function of the Committee

The Science Board shall provide advice primarily to the Commissioner of Food and Drugs (the Commissioner) and other appropriate officials on both general and specific scientific and technical issues as well as emerging issues within the scientific community. Additionally, the Science Board will