4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Technical Electronic Product Radiation Safety Standards Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Technical Electronic Product Radiation Safety Standards Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on October 25, 2016, from 8:30 a.m. to 5 p.m. and October 26, 2016, from 8:30 a.m. to 5 p.m.

ADDRESSES: Gaithersburg Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301-948-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FOR FURTHER INFORMATION CONTACT: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20993-0002, sara.anderson@fda.hhs.gov, 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The general function of the committee is to provide advice and recommendations to the Agency on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Agency for consideration.

On October 25, 2016, the committee will discuss and make recommendations regarding possible FDA performance standards for the following topics: radiofrequency (RF) radiation products, such as microwave ovens and wireless power transfer; laser products, including an update to amendments to the laser rule, light detection and ranging (LIDAR), laser data (Light Fidelity-LiFi)/ energy transfer, illumination applications and infrared applications; sunlamp products including an update on the performance standards amendments; and non-coherent light sources (e.g., LEDs and UVC lamps) including new initiatives.

On October 26, 2016, the committee will discuss and make recommendations regarding possible FDA performance standards for the following topics: International Electrotechnical Commission (IEC) standards versus performance standards for medical devices; computed tomography (CT); radiography and fluoroscopy; diagnostic and therapeutic ultrasound; and radiation therapy.

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 meeting 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 October 14, 2016. Oral presentations from the public will be scheduled between approximately 10 a.m. to 10:30 a.m. and 3 p.m. to 3:30 p.m. on October 25, 2016, and between approximately 10:15 a.m. to 10:45 a.m. and 2:30 p.m. to 3 p.m. on October 26, 2016. 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 October 6, 2016. 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 October 7, 2016.

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 disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 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: September 16, 2016.

Janice M. Soreth,

Acting Associate Commissioner,

Special Medical Programs

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