

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Technical Electronic Products Radiation Safety Standards Committee; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: 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: Technical Electronic Products Radiation Safety Standards Committee.

General Function of the Committee: To provide advice on technical feasibility, reasonableness, and practicality of performance standards for electronic products to control the emission of radiation under 21 U.S.C. 360kk(f).

Date and Time: The meeting will be held on May 22, 2002, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Orhan H. Suleiman, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12399. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear an informal review of ongoing activities associated with electronic products. Following the overview, FDA will discuss its concern about radiation doses associated with x-ray computed tomography (CT), and its current thinking about amending the U.S. performance standard for x-ray CT imaging procedures. Specifically FDA will address possible requirements for: (1) Definition and standardization of CT terminology; (2) display of an index of patient radiation dose that could be automatically recorded within a facility quality assurance program; (3) automatic exposure control through modulation of x-ray tube output according to patient dimensions; and (4) limitation of the x-ray field size to that needed for image formation. In the afternoon, FDA will discuss proposed amendments to the U.S. performance standard for sunlamp products and

certain initiatives of international standards organizations concerning sunlamp products. In the final session, FDA will be considering mandatory standards for x-ray security screening systems; FDA will discuss public health considerations regarding these systems that use ionizing radiation.

Background information on the discussion topics will be posted under the Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC) Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2002 and scroll down to TEPRSSC.)

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 by May 10, 2002. On May 22, 2002, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m., and between 3:15 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 10, 2002, 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.

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 AnnMarie Williams, Conference Management Staff, 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

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

Dated: April 24, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 May 21, 2002, from 8:30 a.m. to 4:30 p.m.

Location: Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Jody G. Sachs or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: In the morning the committee will discuss acute otitis media indication for PREVNAR (Pneumococcal 7-valent Conjugate Vaccine). In the afternoon FDA will present an update to the committee on the GSK Lyme Disease Vaccine (LYMERix).

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 by May 14, 2002. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 1:45 p.m. and between 3:30 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 14, 2002, 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.