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.

[FR Doc. 02–10797 Filed 5–1–02; 8:45 am]

BILLING CODE 4160–01–S

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.

Persons attending FDA 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 Jody G. Sachs or Denise H. Royster 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 23, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–10794 Filed 5–1–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Private Health Insurance Coverage of Immunosuppressive Drugs Survey—New

Public Law 106–310, Section 2101(b) of Title XXI of the Children's Health Act of 2000, states that the Secretary of Health and Human Services shall provide for a study to determine the costs of immunosuppressive drugs provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance cover such costs.

The Health Resources and Services Administration (HRSA) has determined the extent of government insurance coverage for immunosuppressive drugs given to children pursuant to organ transplantation. However, HRSA still does not know the extent of private health insurance coverage for immunosuppressive drugs. Analysis of the Organ Procurement and Transplantation Network (OPTN) database revealed that approximately 45% of pediatric organ transplant recipients list their primary insurer as being private health insurance—this category being the largest insurer of pediatric organ transplant recipients. Little is known about co-payments, limitation on drug usage, etc., in this category of patients.

In order to fulfill the requirements of Section 2101(b), the Division of Transplantation in the Office of Special Programs, HRSA, contracted with the EMMES Corporation to study the costs of immunosuppressive drugs and to conduct a survey to send to approximately 600 families of post-transplant liver and kidney patients who list private health insurance as their primary provider at the time of transplantation. Data collected and analyzed will be reported to Congress. The report will contain information about the extent to which private health insurance covers the cost of immunosuppressive drugs given pursuant to organ transplants and provide recommendations from the Secretary of Health and Human Services about the findings. Once information has been collected and the report to Congress submitted, the information will be incorporated into private databases maintained by the EMMES Corporation which are closely protected and not available to the public. Analytical requests can be made on the data, but requests are subject to an advisory board and the release in any type of personally-identifiable data or standard analytical file will not be available to the public. The Federal Government will not have access to any of the personally-identifiable data. All these measures will assure patient privacy.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Respondents	Number of respondents	Responses per respondents	Hours per response	Total hour burden
Guardians patients	600	1	.75	450
Transplant Centers	143	1	2.5	357.50
Total	743			807.50