orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 12, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m., and between approximately 3:30 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 June 12, 2000, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the June 19, 2000, Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: June 1, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–14370 Filed 6–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Technical Electronic Product Radiation Safety Standards 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: Technical Electronic Product Radiation Safety Standards Advisory 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 42 U.S.C. 263f(f)(1)(A).

Date and Time: The meeting will be held on June 21, 2000, 8:30 a.m. to 5 p.m., and June 22, 2000, 8:30 a.m. to 12 noon.

Location: Quality Suites, Potomac II and III, 3 Research Ct., Rockville, 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: On June 21, 2000, the committee will discuss: (1) A reproposal for amendments to the performance standard for lasers (part 1040 (21 CFR part 1040)), (2) amendments being considered for the sunlamps standard (part 1040), and hear (3) a presentation addressing nonmedical ionizing radiation security systems, (4) a presentation concerning computed tomography fluoroscopy (CT) and the Year 2000 Nationwide Evaluation of X-Ray Trends Survey of CT. On June 22, 2000, the committee will hear: (1) An update on the reengineering of the radiological health program at the Center for Devices and Radiological Health, (2) a presentation on manufacturers' requirements and the medical device approval process, and (3) a presentation regarding how ultrasound diathermy (21 CFR part 1050) is regulated by FDA.

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 June 16, 2000. Oral presentations from the public will be scheduled on June 21, 2000, between approximately 11 a.m. and 11:20 a.m., and between approximately 1:45 p.m. and 2:05 p.m. Oral presentations from the public will be scheduled on June 22, 2000, between approximately 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 16, 2000, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the June 21, 2000, Technical Electronic Product Radiation Safety Standards Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Technical Electronic Product Radiation Safety Standards Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: June 1, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–14369 Filed 6–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1267]

Draft ''Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria'' dated May 2000. The draft guidance document provides recommended questions for deferral of donors at increased risk for malaria. The guidance document also provides the recommendations for donor questioning regarding travel to vacation resorts located in malarious regions. The draft guidance document currently being announced, when finalized, will replace the recommendations in the guidance entitled ''Recommendations for Deferral of Donors for Malaria Risk'' dated July 26, 1994.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 6, 2000.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Recommendations for Donor

Questioning Regarding Possible Exposure to Malaria'' dated May 2000 to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria'' dated May 2000. The draft guidance document recommends questions to be asked of donors to determine possible exposure to malaria. The draft guidance document also provides recommendations for deferral of donors for malarial risk. The recommendations apply only to donations containing intact Red Blood Cells or platelets. Donations used for preparing plasma or plasma derivatives devoid of intact Red Blood Cells or platelets are excluded. The draft guidance document currently being announced, when finalized, will replace the recommendations in the guidance entitled ''Recommendations for Deferral of Donors for Malaria Risk'' dated July 26, 1994.

The draft guidance document represents the agency's current thinking on malarial risks for prospective donors. 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, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by September 6, 2000. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch 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 http://www.fda.gov/cber/guidelines.htm.

Dated: May 18, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–14371 Filed 6–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10003]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection.

Title of Information Collection: Medicare + Choice Beneficiary Appeal Notices, ''Notices of Denial of Medical Services,'' ''Notice of Denial of Request for Payment'' and Supporting Regulations in 42 CFR 422.568.

Form No.: HCFA–10003 (OMB# 0938–NEW).

Use: This collection includes two Medicare + Choice appeal notices, Denial of Service and Denial of Payment. Pursuant to the Social Security Act Section 1852(g)(1)(B), M+C organizations are required to issue notices to Medicare managed care beneficiaries when a request for either medical service or payment is denied. Additionally, the notices inform beneficiaries of their right to file an appeal.

All M+C organizations will be required to use these forms. Neither the Health Care Financing Administration (HCFA) nor the M+C organizations will use such notices to collect and analyze data on M+C beneficiary appeals. They are for information purposes only.

Frequency: On occasion.

Affected Public: Business or other for-profit and Individuals or Households.

Number of Respondents: 29,892.

Total Annual Responses: 29,892.

Total Annual Hours: 2,994.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.