to 4:30 p.m., and August 9, 2001, from 9:30 a.m. to 4 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Hany W. Demian, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on the reclassification of metal on metal total hip arthroplasty devices. Also, the committee will discuss, make recommendations, and vote on premarket approval application (PMA) for a metacarpophalangeal finger joint prosthesis.

Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at http://www.fda.gov/cdrh/panelmtg.html. Material for the August 8 meeting will be posted on August 7, 2001; material for the August 9 meeting will be posted on August 8, 2001.

Procedure: On August 8, 2001, from 9:30 a.m. to 3:30 p.m., and on August 9, 2001, from 9:30 a.m. to 4 p.m., the meeting is open to the public. 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 August 1, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. on August 8, 2001, and between approximately 9:30 a.m. and 10 a.m. on August 9, 2001. On both days, near the end of the committee deliberations for the reclassification petition and the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 1, 2001, 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.

Closed Committee Deliberations: On August 8, 2001, from 3:30 p.m. to 4:30 p.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding present and future FDA issues.

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

Dated: July 20, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–18750 Filed 7–24–01; 3:30 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0274]

Laser Products—Conformance with IEC 60825–1, Am. 2 and IEC 60601–2–22; Final Guidance for Industry and FDA (Laser Notice 50); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Laser Products—Conformance with IEC 60825–1, Am. 2 and IEC 60601–2–22 (Laser Notice 50).'' This guidance document describes the conditions under which laser product manufacturers may introduce into U.S. commerce laser products that comply with the IEC standards 60825–1, as amended, and 60601–2–22. This guidance document also describes additional requirements of the FDA standard and alternate certification statements to be used with such products. This guidance document provides interim relief to manufacturers from conformance with two differing standards and precludes the need for submission of many requests for variances from the FDA standard while FDA harmonizes with many of the IEC requirements for laser products.

DATES: Submit written or electronic comments concerning this guidance by October 24, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Laser Products—Conformance with IEC 60825–1, Am. 2 and IEC 60601–2–22 (Laser Notice 50)'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written or electronic comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the docket number found in brackets in the heading of the document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Jerome Dennis, Center for Devices and Radiological Health (HFZ–341), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4654.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document describes the conditions under which laser product manufacturers may introduce into United States commerce laser products that comply with the IEC standards 60825–1, as amended, and 60601–2–22. This guidance document also describes additional requirements of the CDRH standard and alternate certification statements to be used with such products. CDRH intends to amend its standards for laser products at 21 CFR 1040.10 and 1040.11 to harmonize many of its requirements with those of the IEC 60825–1 and 60601–2–22 standards. Although CDRH began its amendment process in anticipation of the amendment of IEC 60825–1, CDRH is not yet ready to publish an amendment. CDRH has acknowledged the advantages of one set of criteria and requirements worldwide. Amendment 2 to IEC 60825–1 was published in January 2001. As a result, manufacturers distributing products in both the United states and countries that require conformance with or that recognize IEC 60825–1 will have to evaluate the conformance of their products with this standard and often change the hazard classification of their products. These manufacturers are requesting relief from CDRH requirements so that they will have only to comply with one laser product radiation safety standard. This guidance supersedes: ''Labeling of Laser Products, August 15, 1995 (Laser Notice 45).'' See the **ELECTRONIC ACCESS** section for information on this guidance.

FDA is putting this guidance document into effect immediately because the guidance document is presenting a new policy, consistent with public health, that is less burdensome

than current policy. This guidance document is appropriate because of the amendment of IEC 60825–1 and the intent of CDRH to harmonize its requirements with many of those of the IEC standards.

II. Significance of Guidance

This guidance document represents the agency's current thinking on appropriate interim relief for manufacturers from differences between the amendments of the IEC and CDRH radiation safety standards for laser products. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs) regulation, and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a level 1 guidance consistent with the GGPs.

III. Electronic Access

In order to receive ''Laser Products—Conformance with IEC 60825–1, Am. 2 and IEC 60601–2–22; (Laser Notice 50)'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1346) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets/default.htm. Laser Notice 45 may be accessed at www.fda.gov/cdrh/radhlth/index.html under the index heading for ''Lasers, Including Light Shows'' as a ''Notices to Industry.'' Scroll to number 92 in the list of notices.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this guidance by October 24, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance 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.

Dated: July 13, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–18598 Filed 7–25–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: CMS–R–200]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Health Plan Employer Data and Information Set (HEDIS) and Health Outcome Survey (HOS) and Supporting Regulations in 42 CFR 422.152; *Form No.:* CMS–R–200 (OMB# 0938–0701); *Use:* The Centers for Medicare & Medicaid Services (formerly HCFA) collects quality performance measures in order to hold the Medicare managed care industry accountable for the care being delivered, to enable quality improvement, and to provide quality information to Medicare beneficiaries in order to promote an informed choice. It is critical to CMS's mission that we collect and disseminate information that will help beneficiaries chose among health plans, contribute to improved quality of care through identification of improvement opportunities, and assist CMS in carrying out its oversight and purchasing responsibilities; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Individuals or households; *Number of Respondents:* 313,825; *Total Annual Responses:* 313,825; *Total Annual Hours:* 571,488.

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: Melissa Musotto, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 13, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–18662 Filed 7–25–01; 8:45 am]

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