understanding of the nature of the HIV/AID epidemic in Zimbabwe, capacity building and coordination needs among non-governmental ASOs and other partners in Zimbabwe, and understanding of the broader network of supporting organizations and resources dedicated to facilitating the function of ASOs in Southern Africa. This specifically includes description of the public health importance of the planned activities to be undertaken and realistic presentation of proposed objectives and projects.

2. Technical and Programmatic Approach (25 Points)

The extent to which the applicant's proposal demonstrates an understanding of how to assess the needs of an open system with diverse ASOs and other partners including an overall design strategy and including measurable time lines.

The extent to which the proposal addresses regular monitoring and evaluation, and the potential effectiveness of the proposed activities in meeting objectives. This includes developing a plan to assist non-governmental ASOs in assessing their needs, gaps in services, and methods. The extent to which the applicant proposes a system for providing capacity building support to non-governmental ASOs in Zimbabwe.

3. Ability To Carry Out the Project (20 Points)

The extent to which the applicant demonstrates organizational capability to achieve the purpose of the project including experience networking with ASOs in Zimbabwe and familiarity with structure, function, resources and customs of Zimbabwe.

The extent to which the applicant has an existing, formal membership/network that includes the majority of provinces of Zimbabwe, as evidenced by membership and or dues paying lists.

4. Personnel (20 Points)

The extent to which professional personnel involved in this project are qualified, including documented evidence their knowledge of and experience in working with ASOs to promote effective HIV/AIDS care and prevention services by ASOs that deliver services directly.

The extent to which the composition of the applicant's key management and direct staff are indigenous to the population of Zimbabwe.

5. Plans for Administration and Management of Projects (15 Points)

The extent to which the composition of the applicant's board of directors reflects the indigenous population of Zimbabwe, other ASOs, and other relevant partners across Zimbabwe provinces.

The extent to which the applicant's charter, mission, and mandate reflects its role as a key national ASO networking organization. Adequacy of plans for administering the projects including understanding of their organizational capabilities and administrative infrastructure, for example, administrative and fiscal management systems.

6. Budget (Not Scored)

The extent to which itemized budget for conducting the project, along with justification, is reasonable and consistent with stated objectives and planned program activities.

H. Other Requirements

Technical Reporting Requirements

The recipient is required to provide CDC with original plus two copies of:

1. Written quarterly progress reports;
2. Financial status report, no more than 45 days after the end of the budget period; and
3. Final financial and performance reports, no more than 90 days after the end of the project period.
4. Annual audit of these CDC funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.

A fiscal Recipient Capability Assessment may be required with the potential awardee, pre or post award, in order to review their business management and fiscal capabilities regarding the handling of U.S. Federal funds.

Send all reports to the program contact and the Grants Management Specialist, both identified in the ''Where to Obtain Additional Information'' section of this announcement.

For descriptions of the following Other Requirements, see Attachment I in the application kit. Some of the more complex requirements have some additional information provided below:

AR–14 Accounting System Requirements

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 307 of the Public Health Service Act, [42 U. S. C. section 242I], as amended. The Catalog of Federal Domestic Assistance number is 93.941.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Dorimar Rosado, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: (770) 488–2782, E-mail: dpr7@cdc.gov.

For program technical assistance, contact: Michael St. Louis, MD, Global AIDS Program (GAP), Zimbabwe Country Team, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), Zim-CDC AIDS Project Team, 38 Samora Machel Avenue, 2nd Floor, Harare, Zimbabwe, Telephone: 263 4 796040, 796048, Fax: 263 4 796032, E-mail: stlouism@zimcdc.co.zw.

Dated: July 20, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–18632 Filed 7–25–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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 August 8, 2001, from 9:30 a.m.

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