comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

The draft guidance addresses issues pertaining to providing FDA with electronic copies of electronic records subject to part 11 that are accurate, complete, and suitable for FDA inspection, review, and copying. Part 11 requires persons to be able to furnish FDA with electronic copies of electronic records that are subject to part 11. This draft guidance is intended to assist people who must meet this requirement; it may also assist FDA staff who apply part 11 to persons subject to the regulation. However, this draft guidance is not intended to address issues related to electronic records that are submitted to FDA but that are not required to be maintained.

The draft guidance provides specific information on key principles and practices on electronic copies of electronic records, and it addresses some frequently asked questions. However, it is not intended to cover every aspect of generating electronic copies of electronic records that are accurate, complete, and suitable for FDA inspection, review and copying.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on providing FDA with electronic copies of electronic records. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any nonelectronic 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. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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/ohrms/dockets/dockets/dockets.htm*.

Dated: October 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28551 Filed 11–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0011]

Medical Devices; Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA.'' This document provides recommendations for complying with the premarket notification requirements for these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify these devices.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, 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 you request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electric access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 5, 2002 (67 FR 16406), FDA announced the availability of this draft guidance document and invited interested persons to comment on it by July 5, 2002. Also in the **Federal Register** of April 5, 2002 (67 FR 16338), FDA proposed to classify intraoral devices used to control or treat simple snoring and/or obstructive sleep apnea into class II with this guidance document as the special control. This guidance supersedes the draft guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and Obstructive Sleep Apnea; Guidance for Industry and FDA.''

FDA received one comment on the draft guidance from the National Association of Dental Laboratories. We considered this comment and agree that the guidance does not change the regulatory requirements for dental laboratories. We also revised the guidance to clarify how a manufacturer may submit an abbreviated 510(k) when relying on a class II special controls guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on 510(k) submissions for intraoral devices for snoring and/or obstructive sleep apnea. 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 and regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA'' 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 (1378) 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 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.* A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets.*

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–28550 Filed 11–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year 2003 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Funding Availability for Knowledge Dissemination Conference Grants (Short Title: SAMHSA Conference Grants—PA 03–002).

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS), Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT) announce the availability of Fiscal Year (FY) 2003 funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Program Announcement (PA), including Part I, Knowledge Dissemination Conference Grants (Short Title: SAMHSA Conference Grants—PA 03–002), and Part II, General Policies and Procedures Applicable to All SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Est. Funds FY 2003	Est. No. of awards	Project period
Knowledge Dissemination Conference Grants	Jan. 10, 2003 and Sept. 10, 2003 and each Jan. 10 and Sept. 10 thereafter.	$825,000	20–30	3 years

The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of applications received. This program is being announced prior to the annual appropriation for FY 2003 for SAMHSA's programs. Applications are invited based on the assumption that sufficient funds will be appropriated for FY 2003 to permit funding of a reasonable number of applications being hereby solicited. This program is being announced in order to allow applicants sufficient time to plan and prepare applications. Solicitation of applications in advance of a final appropriation will also enable the award of appropriated grant funds in an expeditious manner and thus allow prompt implementation and evaluation of promising practices. All applicants are reminded, however, that we cannot guarantee sufficient funds will be appropriated to permit SAMHSA to fund any applications. This program is authorized under sections 509, 520A and 516 of the Public Health Service Act. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126, page 35962) on July 2, 1993.

GENERAL INSTRUCTIONS: Applicants must use application form PHS 5161–1 (Rev. 7/00). The application kit contains the two-part application materials (complete programmatic guidance and instructions for preparing and submitting applications), the PHS 5161–1 which includes Standard Form 424 (Face Page), and other documentation and forms. Application kits may be obtained from: National Clearinghouse for Alcohol and Drug Information (NCADI), PO Box 2345, Rockville, MD 20847–2345, Telephone: 1–800–729–6686.

The PHS 5161–1 application form and the full text of the activity are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov.*

When requesting an application kit, the applicant must specify the particular activity for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

Purpose: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT) announce the availability of funds for grants to disseminate knowledge about practices within the mental health services and substance abuse prevention and treatment fields and to integrate that knowledge into real-world practice as effectively and efficiently as possible.

Eligibility: Public and domestic private nonprofit organizations, including State and local governments, professional associations, voluntary organizations, self-help groups, consumer and provider services-oriented constituency groups, community based organizations, and faith-based organizations, may apply