Form/respondent	Burden/response (Hrs.)	Number of responses	Total annual burden (Hrs.)
Laboratory Recordkeeping	250.00	55	13,750
Total			1,788,089

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 23, 2003.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 03–2154 Filed 1–29–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0494]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for a data acquisition unit for ceramic dental restoration systems. FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments by March 3, 2003.

ADDRESSES: Submit written comments 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.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), as amended by the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in a guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. List of Petitions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Medical Device Consultants, Inc., on behalf of Sirona Dental Systems GmbH for data acquisition systems used in the computer aided design and milling of dental restorative prosthetic devices, classified under 21 CFR 872.3660, impression material.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Managment Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 15, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–2112 Filed 1–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0018]

Draft Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products.'' This draft guidance recommends a standardized approach for collecting race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA regulated products. The standardized approach being recommended was developed by the Office of Management and Budget (OMB).

DATES: Submit written or electronic comments on the draft guidance by March 31, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Katherine Hollinger, Office of Health Science and Coordination (HF–8), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or

Nancy Derr, Center For Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or

Ilan Irony, Center for Biologics Evaluation and Research (HFM–576), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5378; or

IDE Staff, Center for Devices and Radiological Health (HFZ–403), 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products.'' FDA believes that the use of the OMB race and ethnicity categories will facilitate comparisons across clinical studies analyzed by FDA with data collected by other Federal agencies. Although FDA has long requested race and ethnicity data on subjects in certain clinical trials, the agency is now making recommendations on the categories to use when collecting and reporting the data.

In the final rule entitled ''Investigational New Drug Applications and New Drug Applications'' (demographic rule) (63 FR 6854, February 11, 1998), the agency recommended that sponsors ask subjects in certain clinical trials to identify their racial group and, if desired, to use the OMB categories when collecting race and ethnicity data.

The Department of Health and Human Services (HHS) issued a 1999 report entitled ''Improving the Collection and Use of Racial and Ethnic Data in HHS'' in which HHS announces the adoption of OMB Directive 15 as part of its policy on collecting and reporting data on race and ethnicity. HHS recommended methods for the collection and inclusion of racial and ethnic categories in HHS-funded and HHS-sponsored data collection and reporting systems in all HHS programs, including both health and social services. This HHS policy states that the categories in OMB Directive 15 and its revisions be used when collecting and reporting data in HHS data systems or reporting HHS-funded statistics. The HHS policy was developed to: (1) Help monitor HHS programs, (2) determine that Federal funds are being used in a nondiscriminatory manner, and (3) promote the availability of standard racial and ethnic data across various agencies to facilitate HHS responses to major health and human services issues.

Information on patient safety is reported by Federal agencies using the OMB recommendations. The application of OMB recommendations for the standardized collection and representation of race and ethnicity in clinical trial data is expected to enhance the comparability of data among clinical studies submitted to FDA and with reported health statistics. The recommendations made in this draft guidance are suggested for collecting race and ethnicity data in clinical trials developed to study pharmaceutical products and devices where necessary to determine safety and effectiveness. The agency recommends using more detailed race and ethnicity categories when appropriate to the study or locale, but recommends that the OMB categories be identified for all clinical trial participants when submitting data to the agency. In addition to asking for comments on this guidance generally, FDA specifically is asking for comments on the general applicability of this draft guidance to clinical trials of medical devices.

This draft guidance does not discuss increasing the number of studies in