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Draft Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products.'' This draft guidance recommends a standardized approach for collecting race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA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DATES: Submit written or electronic comments on the draft guidance by March 31, 2003.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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

which subpopulations are exposed to a product. The draft guidance also does not discuss increasing the total number of participants or members of a subpopulation in clinical trials.

This draft guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in sections III and IV of this draft guidance are approved under OMB control number 0910–0014.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on how to collect race and ethnicity data in certain clinical trials for FDA regulated products. 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 mailed 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 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 either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 24, 2003.

Margaret M. Dotzel,

Assistant Commissioner fro Policy.

[FR Doc. 03–2162 Filed 1–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–090–03–9971–EK]

Conservation Helium Sales

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice implementing first Conservation Helium sale.

SUMMARY: The purpose of this action is to implement the terms of the Helium Privatization Act (HPA) of 1996 dealing with the disposal of the Conservation Helium reserve. The Act requires the Department of the Interior *to offer for sale,* beginning no later than 2005, a portion of the Conservation Helium stored underground at the Cliffside Field north of Amarillo, Texas. The Department of the Interior in consultation with the private helium industry has determined that private companies with refining capacity along the crude helium pipeline will need a supply of helium in excess of that available from their own storage accounts and that available from crude helium extractors in the region, and that given the current market, Conservation Helium sold in this sale will likely minimize market disruption. The Bureau just concluded a 30-day comment period in which eight comments were received. The comments were generally supportive with mainly long-term concerns expressed. The Bureau made some minor modifications to address concerns expressed by those comments.

DATES: Submit bids and other documentation as required in notice on or before March 3, 2003.

ADDRESSES: You may submit your bids and other documentation as required in this notice to the Bureau of Land Management, Amarillo Field Office, 810 S. Fillmore, Suite 500, Amarillo, TX 79101, Attention: Crude Helium Sale.

FOR FURTHER INFORMATION CONTACT: Timothy R. Spisak, (806) 356–1002. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

1.01 What Is the Purpose of the Sale?

The purpose of this sale is to begin implementation of the terms of the Helium Privatization Act (HPA) of 1996 dealing with the disposal of the Conservation Helium reserve. The Act requires the Department of the Interior *to offer for sale,* beginning no later than 2005, a portion of the Conservation Helium stored underground at the Cliffside Field north of Amarillo, TX. The Department of the Interior in consultation with the private helium industry has determined that private companies with refining capacity along the crude helium pipeline will need a supply of helium in excess of that available from their own storage accounts and that available from crude helium extractors in the region. This is the first of 12 annual sales that the Department will conduct to dispose of the Conservation Helium stored underground at the Cliffside Field. The annual sales are being conducted in a manner intended to prevent pure helium market disruptions from occurring to end users; shortages of crude helium to pure helium refiners; and an oversupply of crude helium on the market for crude helium extractors. This first sale will be used to test the disposal process with subsequent sales adjusted as needed.

1.02 What Terms Do I Need To Know To Understand This Sale?

Allocated Sale—That portion of the annual sale volume of Conservation Helium that will be set aside for purchase by the crude helium refiners.

Annual Conservation Helium Sale—The sale of a certain volume of Conservation Helium to private entities conducted annually beginning no later than 2005.

Bidder—Any entity or person who submits a request for purchase of a volume of the annual Conservation Helium sale and has met the qualifications contained in part 1.05 in this notice.

BLM—The Bureau of Land Management.

Conservation Helium—The crude helium purchased by the U.S. Government under the authority of the Helium Act of 1960 and stored underground in the Cliffside Field.

Crude Helium—A partially refined gas containing about 70 percent helium and 30 percent nitrogen. However, the helium concentration may typically vary from 50 to 95 percent.

Crude Helium Refiners—Those entities with a capability of refining crude helium and having a connection point on the crude helium pipeline and a valid helium storage contract as of the date of a Conservation Helium sale.

Excess Volumes—Allocated sale volumes not requested by the crude helium refiners.

Helium Storage Contract— A contract between the BLM and a private entity allowing the private entity to store crude helium in underground storage at the Cliffside Field.

HPA— The Helium Privatization Act of 1996.

In-Kind Crude Helium— Conservation Helium purchased by private refiners in exchange for like amounts of pure helium sold to Federal agencies and