

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. VEDESMA

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**Draft Guidance for Industry on the Collection of Race and Ethnicity Data  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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products." This draft guidance recommends a standardized approach for collecting race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA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**DATES:** Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. 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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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.

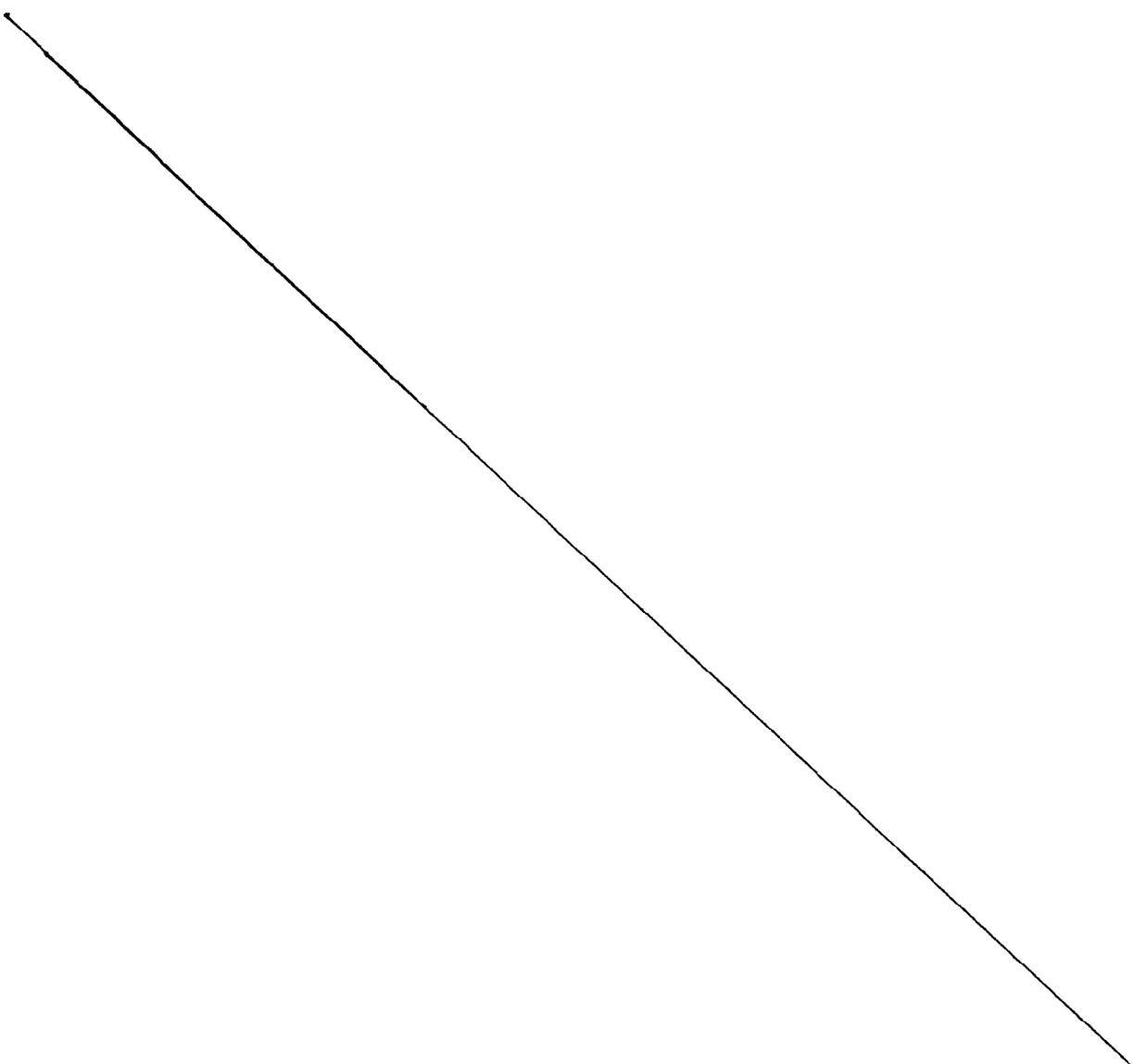
This draft guidance does not discuss increasing the number of studies in which subpopulations are exposed to a product. The draft guidance also does not discuss increasing the total number of participants or members of a subpopulation in clinical trials.

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: 1/24/03  
January 24, 2003.



Margaret M. Dotzel,  
Assistant Commissioner for Policy.

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