

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. 2002D–0018] (formerly 02D–0018)**

### **Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials; 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 guidance for industry entitled “Collection of Race and Ethnicity Data in Clinical Trials.” This guidance provides recommendations on a standardized approach for collecting and reporting race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA regulated products. This document provides guidance on meeting the requirements in the 1998 final rule on Investigational New Drug Applications and New Drug Applications (Demographic Rule) (63 FR 6854, February 11, 1998).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this 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 (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–

1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance to the Division of Dockets Management (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 guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Katherine Hollinger, Office of Women's Health, Office of Science and Health Communication (HF-8), 5600 Fishers Lane, Rockville, MD 20857, 301-827-0935, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), 1401 Rockville Pike, Rockville, MD 20852, 301-827-6210, or

Investigational Device Exemption Staff (HFV-403), Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Collection of Race and Ethnicity Data in Clinical Trials." A draft of this guidance was issued on January 30, 2003 (68 FR 4788). Based on comments received on the draft and the refinement of agency thinking on this topic, FDA has revised the draft guidance and is now issuing a guidance. This guidance is intended to assist sponsors in the collection of race and ethnicity information in clinical trials conducted in the United States and abroad for

certain FDA regulated products using a standardized approach. The standardized approach was developed by the Office of Management and Budget (OMB). FDA believes that the use of the OMB approach will facilitate comparisons across clinical studies analyzed by FDA and data collected by other Federal agencies. Although FDA has long requested the racial and ethnic ancestral origins of subjects in certain clinical trials, the agency is now making recommendations on the methods and categories to use when collecting and reporting 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 announced the adoption of OMB Directive 15 as part of its policy on collecting and reporting data on racial and ethnic ancestral origins.

FDA received several comments in response to the January 2003 draft guidance and has made some clarifying changes in the final version of the guidance. Specifically, we have:

1. Added reference to 21 CFR 314.50(d)(5)(v) to include studies for efficacy.
2. Clarified the traceability/mapping between more granular characterizations for racial and ethnic ancestral origins: “When more detailed characterizations are desired, the use of Race and Ethnicity vocabulary tables located within Health Level Seven’s Reference Information Model Structural Vocabulary Tables is recommended. These tables provide the five and two OMB characterizations traceable to more detailed characterizations and concept ID code sets and this will ensure that traceability is consistent.”
3. Added text to address gaps in the characterization of race and ethnicity: “Where gaps exist in the representation of race or ethnicity categories, sponsors

are encouraged to discuss the race or ethnicity issue with the appropriate review division.”

4. Added text to allow omission of characterization of Hispanic or Latino ethnicity for international clinical trials: “the ethnicity question can be omitted for studies conducted abroad.”

5. Changed the characterization of “Black, of African heritage,” to “Black” for studies conducted abroad.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on collection of race and ethnicity data in clinical trials. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any 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 guidance and received comments are available for public examination in the Division of Dockets Management 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/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 8, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**