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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0018; *Guidance for Industry - Collection of Race and Ethnicity Data in Clinical Trials*

Dear Sir/Madam,

Thank you for the opportunity to review the draft guidance ***Collection of Race and Ethnicity Data in Clinical Trials*** (reference Federal Register listing of 30 January 2003).

Our comments are attached.

Should any clarification of our input be required, please don't hesitate to contact Jenny Peters either by phone (269)-833-8141 or by email (jenny.l.peters@pharmacia.com).

Sincerely,

Pharmacia Corporation

Jenny Peters RPh
Director
Global Regulatory Affairs

02D-0018

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General Comment: Since we are currently required to collect data on race and to summarize it in our analyses, there is minimal additional burden. However, the nature of the data requested, its definitions, and its ultimate use may be problematic.

- **(Line 38-40) In Section I. INTRODUCTION**, it is stated that this guidance "does not discuss increasing the number of studies ... total number of participants ... " Although the guidance does not consider these issues, the mention of them indicates that increasing the number of studies and subjects may be a consequence of collecting this information. This paragraph should be removed; it adds no value and raises a potentially problematic issue.

- **(Line 58) In Section II. BACKGROUND**, it is mentioned that one of the reasons in recommending the use of the OMB race and ethnicity categories is to help ensure consistency in demographic analysis across data collected by other government agencies in the US as well as ICH regions. Two sections of the CFR that discuss foreign data, as well ICH's E5 *Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data*, are referenced.

  The OMB race and ethnicity categories can be used only in the US, not in the EU or in Japan; this is especially true for the ethnicity questions (Hispanic/Latino vs. Not Hispanic/Latino). A definition of the ethnicity varies among the ICH countries, as well as non-ICH countries. There will be more opportunities for the US to utilize foreign clinical data in evaluating safety and efficacy of new drugs in the future. Therefore, it is recommended that the race and ethnicity categories should be more scientific and globally accepted so that the data comparison becomes more meaningful and provides valuable information in evaluating potential differences or similarities in safety and efficacy of new drugs among population subgroups.

- **(Line 69-95) In Section II. A. Relevance of Population Subgroup Studies**, it is stated that the OMB race and ethnicity categories were not scientifically based designations, but instead were categories describing the socio/cultural construct of our society. However, in the next paragraph, the OMB categories are used to evaluate an influence of the intrinsic factor such as genetic factor etc. during evaluation of safety and effectiveness of FDA-regulated products, which requires science-based data analysis. It is recommended that, if the goal includes gaining scientific information, the race and ethnicity categories should be scientifically based designation.

  The first paragraph states that the categories are not based on scientific principles. It is understandable that the U.S. government wants to sort issues by various socio/cultural groups. However, if there is no scientific basis for examining the effects (either positive or negative) in these groups, doing so may provide an opportunity for identifying differences where none exist. Collecting the data by these definitions is one thing, using it to distinguish effects in different populations is another.

- **(Line 80-95)** This paragraph promotes the perspective that pharmacogenetic data substantiate the OMB categorizations; while true in some cases, it makes the significant omission of more recent research showing markedly different situation. Genetic-based tests should be mentioned and allowed as part of a more extensive demographic characterization of study participants, where appropriate.

- **(Line 97-101)** Although the first sentence in this paragraph is correct, the standardized categories that are required are, to a great degree socio/cultural, rather than racial. The guidance should be scientifically honest in the potential value of this information.

- **(Line 129-133) In Section B. FDA Decision to Recommend Use of the OMB Categories**, it is mentioned that FDA has decided to recommend the OMB categories be used in clinical studies for FDA-regulated products conducted in the US and abroad. Again, the OMB categories are designated describing socio/cultural construct of the US society; therefore, these categories do not appear to be applied to those of the other countries. It is recommended that this subject be brought to the next ICH meeting for discussion.

- **(Line 140-176) In Section III, COLLECTING RACE AND ETHNICITY DATA IN CLINICAL TRIALS**, there are five and two choices in selecting race and ethnicity, respectively. It is recommended to add multi-racial categories to the list so that an individual volunteer would not be forced to choose a single category, and the data collected can be used scientifically.

  It is straightforward to collect the information, but its accuracy may be questionable, particularly in studies conducted outside the United States.

  The terms Hispanic and Latino will not have the same meaning outside the U.S. as they do within the U.S. According to the definition, Spaniards are considered Hispanic, but they are both culturally and racially more similar to French than Mexicans.

  Asking subjects about their race/ethnicity may be very sensitive in many circumstances and could be viewed as a bureaucratic burden. Conducting a study in Japan, e.g., and asking a subject whether they are Hispanic may result in patients taking questionnaires less seriously and compromising other data being collected.

  The difference between "Black or African American" and "Black, of African heritage" is clearly semantic. There is no distinction among the Asian group, which may be more genetically variable. There should be consistency among the classifications that would permit a scientific determination of any ethnic/racial differences.

> There are some other racial groups that do not fit clearly into this guidance. For example Australian Aborigine, they are black in skin color, but are not directly of African Ancestry. What about native New Zealanders (Maori)- that would probably be regarded as Pacific Islander? What about Laplanders? Finally, the Asian racial group might be very wide and could really be subdivided among those peoples derived from the Indian sub-continent and those from East Asian (mongoloid or Sino Malay).

Consequently, for these categories to be valuable globally and to permit identification of ethnic differences, there should be only one set of ethnic/racial categories. These should be defined to permit evaluation of differential ethnic responses to drugs globally, not only among socio/cultural groups within the U.S. It is recommended that this subject be brought to the next ICH meeting for discussion recommending standardized racial/ethnic categories.