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

Re: Docket No. 02D-0018; Draft Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products Availability, *Reference to 68 Federal Register 4788 (January 30, 2003)*

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2001 alone, Bristol-Myers Squibb dedicated $2.1 billion for pharmaceutical research and development activities. The company has nearly 6,000 scientists and doctors committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises more than 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on this FDA Draft Guidance on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products Availability that was published in the Federal Register on 30 January, 2003.
We commend the U.S. FDA for a well-written and helpful document. However, we would like to take this opportunity to offer general comments followed by more specific concerns with the proposal.

General Comments

Bristol-Myers Squibb strongly supports the FDA effort to harmonize on a worldwide basis the categories that are used for the collection of race data.

The guidance does not document with clear evidence the medical basis for the proposed category to be used for the collection of ethnicity data.

Proposed ethnicity and racial categories may be understood differently in different part of the world. Used terminology – like "Latino" – can be confusing outside the United States, while the medical relevance of such category is not demonstrated inside the US.
Ethnicity and racial categories do not appear to be exhaustive.
Clear definition will have to be provided in order to ensure an accurate data collection.
As a conclusion, better-defined categories would ensure a better determination of the safety and efficacy of a product according to ethnicity and racial factors.

Based on past experience, it is known that subject self-reporting of race and ethnicity may lead to a significant rate of refusals.

The collection of multiracial identities for the same subject as opposed to the collection of a subject primary identity will add complexity to the interpretation and the analysis and therefore we do not recommend the collection of multiple racial categories for a same subject.

Specific Comments

The guidance recommends a different description of the Black designation depending on whether the study is performed in the United States or outside the United States. Because many pivotal clinical trials designed to support registration in the U.S. are performed worldwide, it is suggested that the same terminology be used for the collection of race regardless where the trial is conducted. With the aim of defining race in a manner that would be applicable globally and based on the OMB Standards (Appendix 2), it is suggested to define "Black or African American" as "Black, of African heritage or African American."

The racial categories proposed are not exhaustive. In particular indigenous people of non-U.S. countries are not classified. The guidance should recommend how these groups should be included in the proposed categories, or as an added category "other". As an example, the guidance should clarify in which category should Australian Aborigines be classified.

The FDA draft guidance document recommends the terminology "Native Hawaiian or Other Pacific Islander" as a choice for race (Sections III and IV). It is suggested that the terminology not be biased toward an U.S. audience and the category be designated "Native Pacific Islander".

The FDA draft guidance document recommends the terminology "American Indian or Alaska Native" as a choice for race (Sections III and IV). Because many pivotal clinical trials designed to support registration in the U.S. are also performed in Canada, it is suggested that this race choice be designated "North American Indian or Alaska Native."

The guidance should clarify the medical reason to divide out a subject population in Hispanic or Latino versus not Hispanic or Latino ethnicity in order to perform separate analysis of the clinical data.

The requirement that Hispanic or Latino versus not Hispanic or Latino ethnicity be collected even in trials that are conducted entirely outside the U.S. seems contradictory to the spirit of the ICH guidelines. If ethnicity designations, as per the guidance, are to reflect the sociocultural construct of the society, then the proposed category is generally inappropriate outside the United States. In addition the definition of the Hispanic and Latino ethnicity needs to be clarified as to

If an individual can designate him/herself as belonging to more than one racial category this will change the way race will be reported and analyzed. Instead of simple reporting of race into mutually exclusive categories (White, Black, Asian), reporting will have to be made for each category with its complement (e.g. Black/fractional Black versus non-Black, etc). We would prefer the guideline seek a subject's primary race in order to avoid this increased level of complexity in reporting and analysis. We understand however the difficulty to force subjects of mixed origins to choose one option. Therefore, for the purposes of data analysis, we would like to have a separate category for those subjects who choose not to report him/herself as a primary race.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

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