AstraZeneca

Date: MAR 27 2003

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

Re: Docket Number 02D-0018, CDER 200272
Response to FDA Call for Comments
Collection of Race and Ethnicity Data in Clinical Trials

Dear Sir or Madam:

Reference is made to the January 30, 2003 Federal Register notice announcing the request for comments on the draft Guidance for Industry, Collection of Race and Ethnicity Data in Clinical Trials.

AstraZeneca has reviewed this guidance and our comments are attached.

Please direct any questions or requests for additional information to me, or in my absence, to Patricia Patterson, Associate Director, at (302) 885-1539.

Sincerely,

Patricia Patterson for

Judith Molt
Director, Regulatory Affairs
Telephone: (302) 885-0976
Fax: (302) 886-2822

JM\PMP

Enclosure

02D-0018 C11

US Regulatory Affairs
AstraZeneca LP
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Comments from AstraZeneca on the FDA Draft Guidance for Industry collection of Race and Ethnicity Data in Clinical Trials

Comments are summarized below:

General Comments

- Comment 1

  The whole concept of "race" has in later years been challenged based on a new understanding of the human genetic code, which indicates that the genetic differences between two person of the same race or ethnicity is just as great as between two persons of different race or ethnicity.

  References: Nature Genetics 2001 volume 29 no. 3 pp 239-240, 265-69

  Lancet 2001, volume 358. Nov. 3, p 1519

- Comment 2

  The OMB categories were developed for use specifically in the United States and may not be applicable or even well understood outside of the US. In Europe, the mere request to a patient in a clinical trial to classify him/herself in terms of "race" is likely to lead to confusion and sometimes adverse feelings. There is also a very mixed ethnic background in the population in many countries, which would again lead to great uncertainty, both for patients and investigators, when trying to decide the categories as suggested. Therefore, with no commonly agreed criteria for ethnicity outside the United States, it is unlikely that the data collected about race and ethnicity in clinical trials outside the US and especially in Europe would be reliable.

  We therefore recommend, that only for specific trials aimed at investigating if there are specific differences in different populations, eg in kinetics and metabolism between Japanese and Western populations, should we ask the patients to classify themselves according to the suggested criteria. This would also be in harmony with the recommendations by the FDA in the 1998 Demographic Rule.

- Comment 3

  The map between the socio-political OMB categories and the scientific/anthropologic designations of race is not clear-cut and many race and ethnicity categories will not map into the OMB categories. If every pharmaceutical and medical device company develops their own map, it is possible that there would be study-specific differences, program-specific differences, product-specific

differences and company specific differences, as minor variations in mapping will become more divergent over time as data accumulates.

- Comment 4

  The OMB classifications cannot address pharmacogenetic differences between races and ethnic groups. Data analysis based on these classifications would not address intrinsic differences between these groups. Any assumptions made on this analysis would present a distorted and inaccurate picture of any differences and may actually result in decreased patient safety.

- Comment 5

  The collection of race/ethnicity data may potentially violate patient privacy regulations in other parts of the world.

Collection of Race and Ethnicity Data in Clinical Trials		
Section	**Page /or Line Number**	**Comment or proposed replacement text**
I.	1/18	The recommendations apply to "certain" FDA-regulated products. The use of the term "certain" is ambiguous as no further clarification if offered.
II	2/51	FDA regulations require sponsors to present in "certain" marketing applications an analysis of data according to demographic subgroups (age, gender, race), as well as an analysis of modifications of dose or dosage intervals for specific subgroups. The use of the term "certain" is ambiguous as no further clarification is offered.
III	5/152	If respondents are permitted to designate multiracial identity, as described, there should be a relevant choice on the minimum choice list, otherwise there will be such variety as to preclude any logical grouping.