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January 8, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Docket No. 2003N-0529
Comments on Systematically Collecting Race and Ethnicity Data
in Post-marketing Adverse Event Reports

Dear Sir or Madam:

On behalf of 3M Pharmaceuticals, I am writing to register comments to Docket No. 2003N-0529 with regard to the possibility of amending the MedWatch form to collect race and ethnicity data in post-marketing adverse event reports. The FDA request for comments notice was posted in the Federal Register on December 8, 2003. Our comments are attached.

If you need any additional information or have questions regarding the comments, please do not hesitate to call me at 651-737-7119.

Sincerely,

Marie D. Kuker
Manager, Regulatory Affairs
US and International

2003N-0529

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**3M Pharmaceuticals' Comments in response to FDA's Request for Comments
Notice on Systematically Collecting Race and Ethnicity Data in Post-marketing
Adverse Event Reports (Docket No. 2003N-0529)**

Race and ethnicity information is only rarely obtained or obtainable from voluntary reporting. 3M is unaware that any regulatory or scientific decision made by the FDA or any other regulatory agency has ever been based on race and/or ethnicity data gleaned from voluntary reports.

Voluntary or spontaneous reporting is under-reporting. The simpler the reporting process can be made, the higher the chances of receiving reports from physicians and other sources. The addition of race and ethnicity data adds further complexity to an already crowded MedWatch form and might serve to undermine rather than enhance future reporting. For example, in Australia, early versions of the voluntary reporting form ("Blue Card") included race/ethnicity information but the added clutter and the low return yield prompted that country to abandon collection of this information and simplify the reporting form. Even more recently, the Blue Card field for collecting patient height information has been removed since this detail was so rarely provided and because it has been of little analytical value in spontaneous reporting data. In the voluntary reporting domain, simplification of the form seems to be an overriding principle.

Furthermore, in a global context, some countries and regions (e.g. in Europe) strongly object to the collection of race and ethnicity information, as well as other potential identifying information relating to the patient. Given the lack of a global consensus, including in countries with higher spontaneous reporting rates than the USA, collection of such data by the FDA may be an isolated activity and therefore of limited benefit. International differences in data collection also add complexity or inconsistency to global ADR databases and associated standard operating procedures.

It is accepted that there are some well-known pharmacological characteristics associated with race or ethnicity (G6PD deficiency, alcohol dehydrogenase deficiency) but these were not discovered from voluntary reporting.

For all these reasons, 3M is not in favor of the addition of race and ethnicity information to the MedWatch form.