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President

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Draft Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials of FDA Regulated Products.

Docket No.: 02D-0018. Federal Register: January 30, 2003 (Volume 68, Number 20) Page 4788-4789

The National Medical Association (NMA) is pleased to respond to the Food and Drug Administration (FDA) request for comment on the draft "Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials of FDA Regulated Products." We applaud the FDA for its efforts to encourage and standardize the collection of health information in a regulatory environment. The National Medical Association believes that the identification and analysis of such data are important components in the elimination of racial and ethnic health disparities.

We support the Food and Drug Administration's recommendation to use the Office of Management and Budget (OMB) guidelines for collecting race and ethnicity information in clinical trials. Use of the revised OMB guidelines – Policy Directive 15 – will help ensure consistency across studies used to support marketing applications to the FDA and across data collected by other government agencies. It will also be useful in evaluating potential population differences in the safety and efficacy of pharmaceutical products among different population groups.

The Food and Drug Administration recommendation is consistent with efforts to improve the validity of clinical trial data supporting the use of medicines in minority patients. The National Medical Association supports the use of OMB guidelines for the collection of data on race and ethnicity until more scientifically rigorous standards are available.

This guidance is consistent with NMA's Consensus Statements and policy guidelines that recognize race and ethnicity as valuable research variables when used and interpreted appropriately, and which encourage appropriate entities to apply the results from studies of race, ethnicity and health to the planning and evaluation of health services. The National Medical Association is a 108 year-old not-for-profit organization that represents the interests of over 20,000 African-American physicians in the United States. Most of these physicians practice in minority communities where little medical research is conducted due to issues of mistrust and a variety of other reasons. We believe this guidance to be an important first step in reducing health disparities in the United States.

We appreciate the opportunity to comment on this important initiative and look forward to future policies or guidelines recommending methods for analyzing and reporting race and ethnicity data.

Sincerely,

L. Natalie Carroll, M.D.

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