



**NATIONAL ASSOCIATION FOR THE ADVANCEMENT OF COLORED PEOPLE**  
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March 31, 2003

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Re: Draft Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials  
Docket No.: 023-0018  
Federal Register: January 30, 2003 (Volume 68, Number 20) Page 4788-4789

The NAACP Health Advocacy Division is pleased to respond to the Food and Drug Administration request for comment on the draft "Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials."

The NAACP applauds the Food and Drug Administration for its efforts to encourage and standardize the collection of health information in a regulatory environment. We believe that the identification and analysis of such data are important components in the elimination of racial and ethnic health disparities.

The NAACP supports the Food and Drug Administration's recommendation to use the Office of Management and Budget guidelines for collecting race and ethnicity information in clinical trials. Use of the revised Office of Management and Budget guidelines – Policy Directive 15 – will help ensure consistency across studies used to support marketing applications to the Food and Drug Administration and across data collected by other government agencies. We would however suggest that just as there is a penalty for not including women in studies, there should also be such penalties for not including racial minorities. This inclusion 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. We support the use of the Office of Budget and Management guidelines for the collection of data on race and ethnicity until more scientifically rigorous standards are available. This guidance is consistent with the National Medical Association's Consensus Statements and

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policy guidelines, which recognize race and ethnicity as valuable research variables when used and interpreted appropriately and which encourages appropriate entities to apply the results from studies of race, ethnicity and health to the planning and evaluation of health services. 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. We look forward to future policies or guidelines recommending methods for analyzing and reporting race and ethnicity data.

Sincerely,

A handwritten signature in cursive script that reads "W Edwards/ce".

Willarda V. Edwards, MD, MBA  
NAACP Health Advocacy Director

cc: President/CEO Kweisi Mfume  
COO Nelson B. Rivers