The National Alliance for Hispanic Health
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March 24, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Re: Docket No. 02D-0018 — Draft Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products; Availability

To Whom It May Concern:

The National Alliance for Hispanic Health (the Alliance), on behalf of our membership network of health and human service providers delivering services to over 12 million Hispanic health consumers annually, strongly supports the adoption of the above referenced guidance.

The proposed guidance will significantly benefit our understanding of racial and ethnic differences in the effectiveness, safety, and appropriate dosing of pharmaceutical products. By utilizing OMB Directive 15 standards for the collection of racial and ethnic data, the proposed FDA guidance will also facilitate comparison of clinical drug trial data with other health data, expanding our understanding of health and well-being. The Alliance particularly supports the draft guidance recommendation that the two-question format be used for requesting race and ethnicity information, with the ethnicity question preceding the question about race and that such data be self-reported whenever feasible. This approach, following current federal data system practices, will insure the broadest comparability of reported clinical trial data.

To strengthen the draft guidance the Alliance recommends including a reference to studies related to drug metabolism and drug response in Hispanic communities. The Alliance also suggests the addition of a recommendation that clinical trial sponsors report information on elements of the study design that ensures cultural and linguistic access of study participants in compliance with Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency." Please note, suggested text and study references are included as an attachment to this letter for each of the above recommendations.

If the Alliance can provide any additional information, please contact Adolph P. Falcón, Vice President for Science and Policy, at (202) 797-4341. Thank you for your review of these comments and recommendations.

Sincerely,

02D-0018

Jane L. Delgado, Ph.D.
President and CEO
National Alliance for Hispanic Health

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Attachment

Detailed Recommendations Addressing Docket No. 02D-0018
Draft Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products; Availability

Submitted by the National Alliance for Hispanic Health
March 23, 2003

Part II (Background), Section A, paragraph 2, line 88

Edit "of Asian descent..." to read "of Asian descent and Hispanics..."

Part II (Background), Section A, paragraph 2, line 89

Following sentence referencing "Xie 2001" study, add following sentences and add references to "Xie 2001" reference:

Hispanics have been reported to require lower doses and are more prone to side effects at normal doses of both tricyclic antidepressants as well as SSRI antidepressants.[1] In one study, the average dose of antipsychotic medication for Hispanics was half the dose given to Caucasians and African Americans.[2]

Part III (Collecting Race and Ethnic Data in Clinical Trials), line 175

Add the following item:

6. We recommend sponsors provide information on steps taken to ensure cultural and linguistic access to clinical trials, cultural proficiency training of study personnel, qualifications related to conducting studies with racial and ethnic communities, and outreach steps to work with racial and ethnic community-based organizations and agencies.

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[1] Escobar, JI, Tuason VB. Antidepressant agents: a cross-cultural study, *Psychopharmacol Bull.* 1980;16:49-52. Also, Versiani M, Ontiveros A, Mazzoti G, et al. A double-blind comparision of fluoxetine and amitiptyline in the treatment of major depression with associate anxiety (anxious depression). In: Herrerra JM, Lawson WB, Sramck JJ, eds. *Cross Cultural Psychiatry.* New York: Wilely;1999:249-258.

[2] Varner RV, Ruiz P, Small DR. Ethnopsychopharmacology in the public sector. In: Ruiz P, ed. Ethnicity and Psychopharmacology, Washington DC; American Psychiatric Press; 2000:11-129.