

were obtained from the agency's final regulatory impact analysis prepared for these regulations.

Moreover, these estimates assume that every processor will prepare sanitary standard operating procedures and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under these regulations.

Dated: December 1, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0529]

Amending the MedWatch Forms to Collect Postmarketing Adverse Event Data Relating to Race and Ethnicity

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comment on the advantages and disadvantages of systematically collecting race and ethnicity data in postmarketing adverse event reports. FDA is also seeking feedback on whether FDA's MedWatch forms (Forms 3500 and 3500A) should be amended to collect the race and ethnicity data. If the MedWatch forms are amended to collect race and ethnicity data, FDA would like comment on how the forms should be amended and the financial impact of amending the forms on both voluntary and mandatory reporters. FDA is also asking for comment on the implications that collecting such race and ethnicity data would have for international reporting of postmarketing adverse events.

DATES: Submit written or electronic comments on this document by February 6, 2004.

ADDRESSES: Submit written comments on identified questions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. The MedWatch forms are available on

the Internet at <http://www.fda.gov/MedWatch>.

FOR FURTHER INFORMATION CONTACT:

Brenda Evelyn, Office of Special Health Issues (HF-12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4460, bevelyn@oc.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA Regulations

FDA regulations require sponsors to present 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 (21 CFR 314.50(d)(5)(vi)(a)) in certain marketing applications.

B. MedWatch Forms

Medwatch Forms FDA 3500 and 3500A are used by voluntary and mandatory reporters, respectively, to collect information on adverse events, product quality problems, and medication errors that occur during marketed use of FDA-regulated products. The MedWatch forms collect demographic and other information about patients in the patient information section (box A), which includes specific data fields for age (box A.2), sex (box A.3), and weight (box A.4). The forms do not, however, include a unique field to capture data on race and ethnicity. Race and ethnicity data can be collected in box B.7 of the MedWatch forms, however, other information is collected in box B.7, including information on preexisting medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction). In addition, the information captured in this section is in a narrative format and cannot be searched efficiently to extract race and ethnicity data. Thus, current placement of race and ethnicity data in box B.7 of the MedWatch forms limits the ability of FDA to analyze postmarketing adverse event data by race and ethnicity.

C. Office of Management and Budget (OMB) Recommendations and FDA Draft Guidance

In 1997, OMB issued recommendations for the collection and use of race and ethnicity data by Federal agencies (Statistical Policy Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting, 1997). In the **Federal Register** of January 30, 2003, FDA made available for comment a draft guidance for industry entitled "Collection of Race and Ethnicity Data in Clinical Trials"

(68 FR 4788). In the draft guidance, FDA recommends the use of standardized OMB race and ethnicity categories for data collection in clinical trials. The agency's recommendations are intended to ensure consistency in the analyses of demographic subsets across studies and to help evaluate potential differences in the safety and efficacy of pharmaceutical products among population subgroups.

With respect to collection of the data, in the draft guidance, the agency provided the following recommendations:

1. A two-question format should be used for requesting race and ethnicity information, with the ethnicity question preceding the question about race.

2. Study participants should self-report race and ethnicity information whenever feasible, and individuals should be permitted to designate a multiracial identity. When the collection of self-reported designations is infeasible (e.g., because of the subject's inability to respond), we recommend the information be requested from a first-degree relative or other knowledgeable source.

3. For ethnicity, the following minimum choices should be offered:

- Hispanic or Latino
- Not Hispanic or Latino

4. When race and ethnicity information is collected separately, the following minimum choices should be offered for race:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander

- White

5. In certain situations, as directed in OMB Directive 15, more detailed race and ethnicity information may be desired (e.g., White can reflect origins in Europe, the Middle East, or North Africa; Asian can reflect origins from areas ranging from India to Japan). If more detailed characterizations of race or ethnicity are collected to enhance data consistency, these characterizations should be traceable to the five minimum designations for race and two designations for ethnicity listed under numbers 3 and 4 in section I.C of this document.

D. ICH Guidance

In 1998, as part of an international effort among Japan, the European Union, and the United States to harmonize technical requirements for pharmaceutical drug development and regulation (ICH (International Conference on Harmonisation)), FDA published a guidance entitled "E5