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.

[FR Doc. 03–30302 Filed 12–5–03; 8:45 am]

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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

Ethnic Factors in the Acceptability of Foreign Clinical Data'' (63 FR 31790, June 10, 1998). The E5 guidance provides recommendations to permit the clinical data collected in one region to be used in the registration or approval of a drug or biological product in another region, while allowing for the influence of ethnic factors. The E5 guidance defines ethnic factors that could affect drug response in terms of both intrinsic and extrinsic issues. Because there is the potential for differences in the safety and efficacy of pharmaceutical products among population subgroups, the E5 guidance provides a general framework for how to evaluate medicines with regard to ethnic factors.

II. Scope of Discussion

In view of the background information presented in section I of this document, FDA is requesting comment on the advantages and disadvantages of collecting race and ethnicity data in postmarketing adverse event reports. FDA is also seeking feedback on whether the MedWatch forms should be amended to collect this data based on the standardized categories described in section I.B of this document. Specific comments are being sought on the following questions:

1. Should the MedWatch forms (Forms FDA 3500A and 3500) be amended with a special field or fields to capture adverse event data on race and ethnicity?

2. Should MedWatch race and ethnicity data distinguish between self-reported and observer-reported designations? If so, how should the designations be captured?

3. Would collection of race and ethnicity data on the MedWatch forms have an impact on the ICH E2B guidance relating to the electronic submission of adverse event reports (''E2B Data Elements for Transmission of Individual Case Safety Reports'' (63 FR 2396 at 2397, January 15, 1998))?

4. What is the financial impact associated with adding a special field or fields to the MedWatch forms to collect data on race and ethnicity?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–30300 Filed 12–5–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed grant information collection activity or to obtain a copy of the data collection plan and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of grantee functions including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title I Minority AIDS Initiative (MAI) Annual Plan and Title I MAI Annual Report: New

The CARE Act (codified under Title XXVI of the Public Health Service Act) was first enacted by Congress in 1990, and reauthorized in 1996 and 2000. It addresses the unmet health needs of persons living with HIV by funding primary health care and support services that enhance access to and retention in care. The CARE Act funded services reach over 500,000 individuals; after Medicaid and Medicare, it is the largest single source of Federal funding for HIV/AIDS care for low-income, uninsured, and underinsured Americans. Title I under the CARE Act provides emergency assistance to eligible metropolitan areas (EMAs) the most severely affected by the HIV epidemic, for the purpose of providing a continuum of high quality, community-based care for low-income individuals and families with HIV disease.

In response to a Presidential declaration in 1998 that HIV was a severe and ongoing health crisis among minority communities, the Congress directed a portion of fiscal year (FY) 1999 CARE Act funds to a new Minority AIDS Initiative (MAI) to address the disproportionate impact of HIV on African-American and Hispanic communities. Since then, the focus has been broadened to include all racial and ethnic minority communities. HRSA disburses the Title I component of MAI funds among the 51 EMAs based on a congressionally mandated formula.

The Congress has directed that Title I MAI funds be used through established local planning council processes to improve HIV-related health outcomes for communities of color and reduce existing health disparities. Improved health outcomes include reducing HIV transmission, morbidity and opportunistic disease, and improving life expectancy.

The Title I MAI Annual Plan (Plan) and Title I MAI Annual Report (Report) are designed to collect information from grantees on MAI-funded services, the number and demographics of clients served, and client-level outcomes. This information is needed to monitor and assess: (a) Increases and changes in the type and amount of HIV/AIDS health care and related services being provided to each disproportionately impacted community of color; (b) increases in the number of persons receiving HIV/AIDS services within each racial and ethnic community; and (c) the impact of the Title I MAI funded services in terms of client-level and service-level health outcomes. This information also will be used to plan new technical assistance and capacity development activities, and inform the HIV/AIDS Bureau/HRSA policies and program management.

The Plan and Report will be transmitted by mail and electronically to all Title I grantees and made available through the HRSA web site. Two alternatives will be provided to grantees for submitting Plans and Reports electronically: a designated mailbox for e-mailed electronic reports and a web-based reporting option. The Plan and