official of the organization applying for the grant who has authority to obligate the organization legally. The applicant's legal name as required on the SF–424 (Item 5) must match that listed as corresponding to the Employer Identification Number (Item 6);

(b) The application must include a project narrative that meets requirements set for in this announcement.

(c) The application must contain documentation of the applicant's tax-exempt status as indicated in the ''Additional Information on Eligibility'' section of this announcement.

OCS Evaluation of Applications

Applications that pass the initial OCS screening will be reviewed and rated by a panel based on the program elements and review criteria presented in relevant sections of this program announcement.

The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application. The review panel awards points only to applications that are responsive to the program elements and relevant review criteria within the context of this program announcement.

The OCS Director and program staff use the reviewer scores when considering competing applications. Reviewer scores will weigh heavily in funding decisions, but will not be the only factors considered.

Applications generally will be considered in order of the average scores assigned by the review panel. Because other important factors are taken into consideration, highly ranked applications are not guaranteed funding. These other considerations include, for example: the timely and proper completion by the applicant of projects funded with OCS funds granted in the last five (5) years; comments of reviewers and government officials; staff evaluation and input; amount and duration of the grant requested and the proposed project's consistency and harmony with OCS goals and policy; geographic distribution of applications; previous program performance of applicants; compliance with grant terms under previous HHS grants, including the actual dedication to program of mobilized resources as set forth in project applications; audit reports; investigative reports; and applicant's progress in resolving any final audit disallowance on previous OCS or other Federal agency grants.

VI. Award Administration Information

1. Award Notices: 90 days after the due date of applications. Following approval of the application selected for funding, ACF will mail a written notice of project approval and authority to draw down project funds. The official award document is the Financial Assistance Award that specifies the amount of Federal funds approved for use in the project, the project and budget period for which support is provided and the terms and conditions of the award.

ACF will notify unsuccessful applicants after the award is issued to the successful applicant.

2. Administrative and National Policy Requirements: 45 CFR part 74.

3. Special Terms and Conditions of Awards: None.

4. Reporting Requirements.

Programmatic Reports: Semi-annually.

Financial Reports: Semi-annually.

Special Reporting Requirements: None.

VII. Agency Contacts

Program Office Contact: Margaret Washnitzer, Office of Community Services, 370 L'Enfant Promenade, SW., Suite 500 West,Aerospace Building, Washington, DC 20447–0002,Email: *mwashnitzer@acf.hhs.gov,*Telephone: (202) 401–9333.

Grants Management Office Contact: Daphne Weeden, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Aerospace Building, Washington, DC 20447–0002, Email: *dweeden@acf.hhs.gov,* Telephone: (202) 401–2344.

VIII. Other Information

Paperwork Reduction Act of 1995 (Pub. L. 104–13): Under the Paperwork Reduction Act of 1995, Pub. L. 104–13, the Department is required to submit to the Office of Management and Budget (OMB) for review and approval of any reporting and record keeping requirements in regulations including program announcements. This program announcement does not contain information collection requirements beyond those approved for ACF grant applications under the Program Narrative Statement by OMB (Approval Numbers: 0348–0043, 0348–0044, 034800040, 0348–0046, 0925–0418 and 0970–0139).

Public reporting burden for this collection is estimated to average 25 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection of information.

The project description is approved under OMB control # 0970–0139 which expires 12/31/03.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: November 24, 2003.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 03–30392 Filed 12–5–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0525]

Agency Information Collection Activities: Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point; Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements for applying hazard analysis and critical control point (HAACP) procedures for safe and sanitary processing for processors of fruit and vegetable juice.

DATES: Submit written or electronic comments on the collection of information by February 6, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management

Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice (OMB Control Number 0910–0466)—Extension

These regulations mandate the application of HACCP procedures to fruit and vegetable juice processing. HACCP is a preventative system of hazard control that can be used by all food processors to ensure the safety of their products to consumers. A HACCP system of preventive controls is the most effective and efficient way to ensure that these food products are safe. FDA's mandate to ensure the safety of the nation's food supply is derived principally from the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged; under 21 U.S.C. 371, the act authorizes the agency to issue regulations for its efficient enforcement. The agency also has authority under the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another other State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety. Through these regulations, FDA is implementing its authority under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
120.6(c) and 120.12(a)(1) and (b)	1,875	365	684,375	0.1	68,438
120.7, 120.10(a), and 120.12(a)(2), (b), and (c)	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) and 120.12(a)(4)(ii) and (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv), 120.11(a)(2), and 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b)	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d)	308	1	308	4	1,232
Total					358,466

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 provides a breakdown of the total estimated annual recordkeeping burden. The estimates in this table have been reviewed by the agency's HACCP experts, who have practical experience in observing various processing operations and related recordkeeping activities.

The burden estimates in table 1 are based on an estimate of the total number of juice manufacturing plants (i.e., 2,300) affected by the regulations. Included in this total are 850 plants currently identified in FDA's official establishment inventory plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers. The total burden hours are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers

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]

BILLING CODE 4160–01–S

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