

their commitment to the success of this program. The WHO represents a key stakeholder in the implementation of the program; providing unique functions, technical and scientific expertise, and capabilities that no other organization in the world has.

**Additional Information:** The agency program contact is Dr. Michael Perdue, whom can be contacted at (202) 260-0966 or [Michael.Perdue@hhs.gov](mailto:Michael.Perdue@hhs.gov).

Dated: August 3, 2010.

**Nicole Lurie,**

*Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: The Stem Cell Therapeutic Outcomes Database (OMB No. 0915-0310)—Extension

The Stem Cell Therapeutic and Research Act of 2005 provides for the collection and maintenance of human cord blood stem cells for the treatment of patients and research. The Health Resources and Services Administration's (HRSA) Healthcare Systems Bureau (HSB) has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain recordkeeping and reporting requirements in order to perform the functions related to hematopoietic stem cell transplantation under contract to the Department of Health and Human Services (HHS). The Act requires the Secretary of HHS to contract for the establishment and maintenance of information related to patients who have received stem cell

therapeutic products and to do so using a standardized, electronic format. Data are collected from transplant centers in a manner similar to the data collection activities conducted by the Center for International Blood and Marrow Transplant Research (CIBMTR) and are used for ongoing analysis of transplant outcomes. HRSA uses the information in order to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation, and to provide the Secretary with an annual report of transplant center-specific survival data. The burden table for the year 2011 shows there will be approximately 12,800 annual follow-up assessments due for the Blood Stem Cell Transplantation Program's Stem Cell Therapeutic Outcomes Database. The 2007 30-Day Federal Register notice included total burden hours of 32,040 and 225 respondents. The burden table below includes 38,700 total burden hours and 200 respondents. The increase in burden is due to an increase in the annual number of transplants. The number of respondents has decreased due to some centers no longer performing unrelated stem cell transplants and some centers are no longer in business.

The estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per Response	Total burden hours
Baseline Pre-TED (Transplant Essential Data) .....	200	30	6,000	0.85	5,100
Product Forms (includes Infusion, HLA, and Infectious Disease Marker inserts) .....	200	20	4,000	1.5	6,000
100-Day Post-TED .....	200	30	6,000	0.85	5,100
6-Month Post-TED .....	200	25	5,000	1.00	5,000
12-Month Post-TED .....	200	23.5	4,700	1.00	4,700
Annual Post-TED .....	200	64	12,800	1.00	12,800
Total .....	200	.....	38,500	.....	38,700

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: August 5, 2010.

**Wendy Ponton,**

*Director, Office of Management.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0411]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables

**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 the information collection provisions in the guidance document entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables."

**DATES:** Submit either electronic or written comments on the collection of information by October 12, 2010.