

immediately in accordance with § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the recent cases of botulism linked to refrigerated carrot juice. This guidance represents the agency's current thinking on important practices for ensuring the safety of refrigerated carrot juice and other low-acid refrigerated juices subject to the juice HACCP regulation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

## II. Comments

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

## III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: May 25, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-10792 Filed 6-4-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0213]

### Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Receipt Date; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Receipt Date." This draft guidance provides information on what FDA will consider to be the receipt date for certain submissions provided in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The receipt date of these submissions has a number of important regulatory implications. Under the draft guidance, FDA will not consider a submission to be received until it has passed a technical validation check to ensure that the submission can be opened, processed, and archived.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 6, 2007.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

### FOR FURTHER INFORMATION CONTACT:

Gary Gensinger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1112, Silver Spring, MD 20993-0002, 301-796-0589; or

Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM-25), 11400 Rockville Pike, Rockville, MD 20852, 301-827-5132.

## SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Receipt Date." This draft guidance provides information on what FDA will consider to be the receipt date for submissions provided in electronic format to CDER and CBER. When FDA receives a submission, the receipt date is used to determine important regulatory milestones (e.g., 30-day safety review cycle for an investigational new drug application, review performance goal date for a new drug application or biologics license application). Occasionally, however, submissions in electronic format have technical deficiencies that prevent FDA from being able to open, process, and archive them. When this occurs, FDA's review cannot begin until these technical deficiencies are corrected. To encourage sponsors to ensure that electronic submissions are free of technical deficiencies that can delay FDA review of the submission, FDA is changing its policy on the receipt date for submissions provided in an electronic format. The guidance provides that FDA will not consider a submission to be received until it has passed a technical validation check to ensure that the submission can be opened, processed, and archived.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on determining the receipt date for submissions in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-10780 Filed 6-4-07; 8:45 am]

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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, 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: Scholarships for Disadvantaged Students Program—(OMB No. 0915-0149)—Reinstatement

The Scholarships for Disadvantaged Students (SDS) Program has as its purpose the provision of funds to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions and nursing programs.

To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the Public Health Service Act). A school must meet the eligibility criteria to demonstrate that the program has achieved success based on the number and/or percentage of disadvantaged students who graduate from the school. In awarding SDS funds to eligible schools, funding priorities must be given to schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act).

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Application .....	500	1	20	10,000
Report .....	500	1	1	500
Total .....	500	.....	.....	10,500

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Karen Matsuoka, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 24, 2007.

**Caroline Lewis,**

*Associate Administrator for Management.*

[FR Doc. E7-10749 Filed 6-4-07; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[Docket No. DHS-2007-0027]

#### Privacy Act; IDENT System of Records

**AGENCY:** Privacy Office, Office of the Secretary, Department of Homeland Security.

**ACTION:** Notice of updated Privacy Act system of records notice.

**SUMMARY:** The Department of Homeland Security is republishing the Privacy Act

system of records notice for the Automated Biometric Identification System in order (1) to add a category of records that comprises unique personal identifiers that links individuals with their encounters, biometrics, records, and other data elements and (2) to add a new routine use consistent with Office of Management and Budget Memorandum M-07-16, Attachment 2 that permits DHS to be in the best position to respond in a timely and effective manner in the event of a data breach. This republished system of records notice will replace the previously published system of records notice for the Automated Biometric Identification System, **Federal Register** on July 27, 2006 (71 FR 42651).

**DATES:** Written comments must be submitted on or before July 5, 2007.

**ADDRESSES:** You may submit comments, identified by DOCKET NUMBER DHS-2007-0027 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 1-866-466-5370.
- *Mail:* Hugo Teufel III, Chief Privacy Officer, Privacy Office, Department of

Homeland Security, Washington, DC 20528.

#### FOR FURTHER INFORMATION CONTACT:

Claire Miller, US-VISIT Acting Privacy Officer, Department of Homeland Security, Washington, DC 20528. For privacy issues please contact: Hugo Teufel III, Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

**SUPPLEMENTARY INFORMATION:** In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) is publishing a revision to an existing Privacy Act system of records known as Automated Biometric Identification System (IDENT). The notice for these systems of records was last published in the **Federal Register** on July 27, 2006 (71 FR 42651).

DHS is republishing IDENT in order (1) to add a category of records that comprises unique personal identifiers that links individuals with their encounters, biometrics, records, and other data elements and (2) to add a new routine use consistent with Office of Management and Budget Memorandum M-07-16, Attachment 2 that permits DHS to be in the best position to respond in a timely and effective