Proposed Project

1. Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients Who Receive Blood That May Have Contained Hepatitis C Virus—NEW—National Center for Infectious Disease (NCID)—The Food and Drug Administration (FDA) has recently issued guidelines for notification of persons who received blood or blood components from donors who subsequently tested positive for antibody to hepatitis C virus (anti-HCV) using a licensed multiantigen assay.[1] Blood collection establishments will identify potentially HCV-contaminated blood products and inform transfusion services of these units. The transfusion services will then attempt to notify the recipients of these products and encourage these recipients to be tested for HCV infection. CDC, in collaboration with the Agency for Health Care Policy and Research (AHCPR) and the FDA, has been charged with the responsibility of evaluating this nationwide notification process. The objective of this study is to evaluate the effectiveness of the targeted lookback for identifying persons infected with HCV, obtaining appropriate medical follow-up, and promoting healthy lifestyles and behaviors. The evaluation has three specific aims:

1. Determine the effectiveness of targeted lookback for identifying prior transfusion recipients with HCV infection, including the proportion of recipients identified who are ultimately tested, the proportion of those tested who are HCV positive, the reasons persons do not receive notification, and the reasons persons do not avail themselves of testing.

2. Determine the effectiveness of targeted lookback for encouraging and obtaining appropriate medical follow-up and promoting healthy lifestyles and behaviors among persons found positive for HCV infection, including proportion of HCV-positive persons who seek medical evaluation and outcome of that evaluation (severity of liver disease, anti-viral therapy, quality of counseling), and reactions/impact of notification on HCV-negative persons.

3. Determine the cost-effectiveness of targeted lookback, including resources (cost, personnel, etc.) utilized by blood collection groups and transfusion services for implementation and costs of medical evaluation and management.

The evaluation will comprise the following components:

1. A nationwide survey of blood collection establishments.

2. A nationwide survey of transfusion services.

3. A follow-up study of transfusion recipients presumed to have been notified of their potential HCV exposure. This detailed study will involve contacting and interviewing transfusion recipients from a sample of transfusion services in defined geographic areas.

4. A follow-up study of notified transfusion recipients who obtain HCV testing offered by blood collection centers.

The total annual burden hours are 12,040.

Respondents	Number of respondents	Number of responses/respondents	Avg. burden/response (in hours)
Blood collection establishments	140	1	5
Transfusion services	5,000	1	5
Transfusion recipients (first telephone contact)	5,000	1	0.2
Transfusion recipients (second telephone contact)	2,000	1	0.5
Transfusion recipients (follow-up interview and study)	200	3	0.5
Transfusion recipients (first interview of recipients tested at ARC/ABC)	500	1	0.2
Transfusion recipients (follow-up interview and study of recipients tested at ARC/ABC)	100	3	0.5

Dated: October 4, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–26272 Filed 10–7–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0780]

Agency Information Collection Activities; Announcement of OMB Approval; Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 26, 1999 (64 FR 40377), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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

[1] Food and Drug Administration. Guidance For Industry. Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV. Rockville, MD: Center for Biologics Evaluation and Research, FDA; September 1998.

number. OMB has now approved the information collection and has assigned OMB control number 0910–0037. The approval expires on September 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–26221 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0926]

Agency Information Collection Activities; Announcement of OMB Approval; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Regulations Under the Federal Import Milk Act'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 12, 1999 (64 FR 44019), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0212. The approval expires on September 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–26223 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Training on Electronic Records; Electronic Signatures; Satellite Conference; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of satellite conference and public meeting.

The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Center for Biologics Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and the Center for Veterinary Medicine) is announcing the following satellite conference and public meeting entitled ''Industry Training on 21 CFR Part 11.'' The topics to be discussed are current good manufacturing practices, electronic recordkeeping requirements, validation of electronic recordkeeping systems, and the answers to frequently asked questions.

Date and Time: The satellite conference and public meeting will be held on Thursday, October 21, 1999, 1 p.m. to 4 p.m., eastern standard time.

Contact: Laura C. Woolf, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–3840, FAX 301–827–3843, e-mail: woolf@cber.fda.gov.

SUPPLEMENTARY INFORMATION: The satellite conference announced in this document is a repeat of the satellite conference at the public meeting announced in the **Federal Register** of December 14, 1998 (63 FR 68778). The satellite conference is intended to inform FDA-regulated industries, and especially, small business about the requirements for electronic recordkeeping according to 21 CFR part 11 and to provide for a dialogue with FDA. The satellite conference addresses the requirements of both the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) that mandates outreach activities by Government agencies directed to small businesses and section 406(b) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) that calls for involvement of FDA with its stakeholders in cooperative activities to ensure the quality of marketed products.

There are no meeting sites and registration is not necessary for the satellite conference and public meeting. To view the satellite conference, companies with satellite capability will need to downlink the coordinates. The coordinates are as follows: C Band Galaxy 6 @ 99 west Transponder 20.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–26222 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 28, 1999, 8:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on a premarket notification for an over-the-