

advantage of their existing statutory authority to promulgate and enforce standards and regulations that are responsive to the hazardous conditions identified by the Research Agenda developed by this Task Force. Agency responsiveness to the Agenda, however, depends largely on the means by which participation, coordination, and accountability among the agencies are effected. Revision of agency statutes to authorize specifically the prevention and remediation of take-home contamination, especially through revision of the factors used to establish the prioritization schemes used by EPA and ATSDR, should be considered by Congress only if the agencies find it difficult to respond effectively to the Research Agenda.

#### **Response From the National Institute for Occupational Safety and Health (NIOSH)**

NIOSH supports the research agenda proposed by the Workers' Family Protection Task Force in this report. The recommended research priorities fit within the framework of the National Occupational Research Agenda (NORA) and particularly its priority area "Special Populations at Risk." This plan, developed by NIOSH and more than 500 public and private partners and stakeholders, includes priorities for addressing allergic and irritant dermatitis; asthma and chronic obstructive pulmonary disease; fertility and pregnancy abnormalities; infectious diseases; control technology and personal protective equipment; and many other areas highlighted by the Task Force for consideration. NIOSH supports the recommendations of the Task Force and welcomes public comment on the proposed research agenda.

Dated: January 30, 1998.

#### **Linda Rosenstock,**

*Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).*

[FR Doc. 98-2824 Filed 2-4-98; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 97N-0264]

#### **Agency Information Collection Activities; Announcement of OMB Approval**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Devices: Substantial Equivalence 510(k) Summaries and 510(k) Statements Premarket Notification" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. 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 16, 1997 (62 FR 38098), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0281. The approval expires on September 30, 2000.

Dated: January 30, 1998.

#### **William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-2910 Filed 2-4-98; 8:45 am]

BILLING CODE 4160-01-F

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 98D-0004]

#### **Guidance for Reviewers on Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for reviewers entitled "Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act." The guidance is intended to clarify the administrative processes that will be followed in implementing the Food and Drug Administration Modernization Act of 1997 (the FDAMA).

**DATES:** General comments on the agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance document entitled "Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFD-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a guidance document for reviewers entitled "Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act." Section 125 of title I of the FDAMA (Pub. L. 105-115), signed into law by President Clinton on November 21, 1997, repealed section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357). As a result of the repeal of section 507 of the act, which took effect immediately, several of the agency's administrative processes for reviewing and approving antibiotic drug applications must be changed. This guidance document is intended to clarify several of the administrative processes that will be followed in implementing section 125 of the FDAMA.

This guidance document represents the agency's current thinking on the implementation of the repeal of section 507 of the act. 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 statute, regulations, or both.

Interested persons may submit written comments on the guidance document to the Dockets Management Branch (address above). Two copies of any 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. The guidance document and received comments may be seen in the office above between 9

a.m. and 4 p.m., Monday through Friday.

Copies of this guidance document are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm."

Dated: January 28, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98-2754 Filed 2-4-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration [HCFA-2728]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Form No.:* HCFA-2728; *Use:* This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law. *Frequency:* Quarterly, Weekly, Semi-annually, Monthly, and Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 60,000; *Total Annual Responses:* 60,000; *Total Annual Hours:* 25,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 27, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.*

[FR Doc. 98-2861 Filed 2-4-98; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration [HCFA-174]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Quality Assurance for Phase II of the Home Agency Prospective Payment

Demonstration; *Form No.:* HCFA-174; *Use:* This instrument will be used to collect information to continue monitoring the quality of care provided by agencies participating in Phase II of the Home Health Agency Prospective Payment Demonstration. *Frequency:* Monthly; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 20,520; *Total Annual Responses:* 53,352; *Total Annual Hours:* 6,669.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 27, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.*

[FR Doc. 98-2862 Filed 2-4-98; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Cancer Institute Special Emphasis Panel (SEP) meeting:

*Name of SEP:* In Vitro Screening and Evaluation of Chemicals and Preclinical Drugs for In Vivo Toxicology Selection.

*Date:* February 17, 1998.

*Time:* 9:00 a.m. to Adjournment.

*Place:* Executive Plaza North, Conference Room H, 6130 Executive Boulevard, Bethesda, MD 20892.

*Contact Person:* Courtney M. Kerwin, Ph.D., M.P.H., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 630I, 6130 Executive Boulevard, MSC 7405, Bethesda, MD 20892-7405, Telephone: 301/496-7421.