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 reinstatement 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 of information listed below.

With respect to the following collection of information, FDA invites comments on: (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.

Petition For Administrative Reconsideration of Action—21 CFR Part 10.33—(OMB Control Number 0910–0192)—Reinstatement

Section 10.33 (21 CFR 10.33), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may petition the Commissioner of Food and Drugs (the Commissioner) for reconsideration of an agency's action. A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. Each petition must be submitted no later than 30 days after the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, state or local governments, not-for-profit institutions, and businesses or other for-profit institutions.

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

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.33(b)	7	1	7	100	700

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

The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative reconsideration of an action estimate approximately seven requests being received by the agency annually, each requiring an average of 100 hours preparation time.

Dated: December 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32805 Filed 12–15–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0182]

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 ''Transmittal of Labels and Circulars, Form FDA 2567'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 19, 1997 (62 FR 49244), 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 0910–0039. The approval expires on November 30, 2000.

Dated: December 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32808 Filed 12–15–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F, of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services, Health Care Financing Administration (HCFA), (49 Federal Register 34247, dated September 6, 1984) is amended to include the following delegation of authority from the Secretary to the Administrator for Title XXI of the Social Security Act.

The specific amendments to Part F are described below:

I. Section F.30., Delegations of Authority is amended by adding the following paragraph: SS. The authority vested in the Secretary under Title XXI of the Security Act (42 U.S.C. 1397aa *et seq.*).

Limitation: No State plan or amendment shall be finally disapproved without consultation and discussion by the Administrator with the Secretary.

II. Section F.30., Delegations of Authority, paragraph RR is revised to include title XXI, the revised paragraph reads as follows:

RR. The authority vested in the Secretary or that may become vested in the Secretary, and not otherwise delegated, limited, or reserved, to conduct studies and demonstration projects, as directed by Congress, that relate to the programs established by Title XI of the Social Security Act (Act), insofar as they relate to the mission of the Health Care Financing Administration (HCFA), and Titles XVIII, XIX, and XXI. This delegation encompasses the authority to approve related program activities required by the studies and demonstration projects if such authority is or becomes vested in the Secretary and is not otherwise delegated, limited, or reserved. These activities include, but are not limited to, direct performance, entering into contracts or cooperative agreements, making grants, approving payments for contracts, cooperative agreements, and grants and approving authorized waivers of compliance with certain requirements of titles XI, XVIII, and XIX and XXI of the Act when such actions are for the purpose of conducting studies and demonstration projects.

This delegation shall be exercised under the Department's existing delegation of authority and policy on regulations. In addition, I hereby ratify and affirm any actions taken by the Administrator or other HCFA officials which, in effect, involved the exercise of this authority prior to the effective date of this delegation. This delegation is effective immediately.

Dated: December 2, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–32747 Filed 12–15–97; 8:45 am]

BILLING CODE 4120–03–M

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 National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Cancer Education Program, Telephone Conference Call.

Date: December 18, 1997.

Time: 3:30 p.m. to Adjournment.

Place: National Cancer Institute, Executive Plaza North, Room 611A, 6130 Executive Boulevard, Bethesda, MD 20892.

Contact Person: Mary Bell, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 611A, 6130 Executive Boulevard, Bethesda, MD 20892, Telephone: 301/496–7978.

Purpose/Agenda: To review, discuss and evaluate grant applications.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Grant applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower, 93.399, Cancer Control.)

Dated: December 10, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–32745 Filed 12–15–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

National Institutes of Health

Electric and Magnetic Fields Research and Public Information; Dissemination (EMFRAPID) Program; Environmental Toxicology Program, Office of Special Programs; National Institute of Environmental Health Sciences, National Institutes of Health

NOTICE: Second EMF Science Review Symposium—EMFRAPID Program.

Background

The National Institute of Environmental Health Sciences (NIEHS) and the Department of Energy (DOE) are coordinating the implementation of the Electric and Magnetic Fields (EMF) Research and Public Information Dissemination (RAPID) Program. EMFRAPID was established by the 1992 Energy Policy Act (Section 2118 for Public Law 102–486) which was signed in October 1992. This five-year effort is designed to determine the potential effect from exposure to 60 Hz electric and magnetic fields on biological systems, especially those produced by the generation, transmission and use of electric energy. DOE is responsible for characterizing field exposures and for mitigating exposures which may be hazardous. The NIEHS is responsible for the development and implementation of a research program on the possible human health effects of electric and magnetic fields (EMF). The RAPID Program requires the NIEHS to report on the extent to which exposure to electric and magnetic fields adversely affects human health.

The NIEHS has three groups that assist in managing and directing the science portion of RAPID and who will provide guidance on reporting on the health effects of electric and magnetic fields. The first, known as the Interagency Agency Committee on Electric and Magnetic Fields (IAC) is composed of representatives from 10 federal agencies with responsibilities related to electric and magnetic fields (DOE, NIEHS, the Environmental Protection Agency (EPA), the Department of Defense (DOD), the Occupational Safety and Health Administration (OSHA), the National Institute of Standards and Technology (NIST), the Department of Transportation (DOT), the Rural Electrification Administration (REA), the Department of the Interior (DOI), and the Federal Energy Regulatory Commission (FERC)). The IAC, established by the President of the United States, must also prepare a final report for Congress.

The second is the National Electric and Magnetic Field Advisory Committee (NEMFAC). NEMFAC consists of representatives from public interest groups, organized labor, state governments, academia, and industry. This groups advises DOE and NIEHS on the design and implementation of the program. NEMFAC also provides recommendations to the IAC.

Finally, the NIEHSA has an internal EMF Steering Committee (SC) consisting of senior scientists with broad programmatic responsibilities and a broad scientific perspective. The SC manages all aspects of the EMFRAPID Research Program at the NIEHS.

NIEHS Report on Human Health Effects of EMF

The report development process combines a critical evaluation of the scientific literature with an assessment of the strength of the evidence for human health effects resulting from EMF exposures. To accomplish the initial part of this process, the NIEHS is convening a series of open, public symposia on science related to EMF exposures and their biological effects for these study areas: theoretical/*in vitro* research findings, epidemiological results, and *in vivo*/clinical laboratory findings. The symposia (March 1997, January 1998, and April 1998) provide