STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Draft Advisory Opinion 2000–24; Alaska Democratic Party by counsel, Neil Reiff.

Statements of Reasons—Requests to Deny Certification of Public Funds to Patrick J. Buchanan and Ezola Foster (LRA#598/599).

Notice of Disposition of Petition for Rulemaking Filed by the Project on Government Oversight.

Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Acting Secretary of the Commission.

[FR Doc. 00–27654 Filed 10–24–00; 11:49 am]

BILLING CODE 6715–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics; Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Time and Date: November 28, 2000—9 a.m.–5 p.m. EDT.

November 29, 2000—10:15 a.m.–3:30 p.m. EDT.

Place: Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 705A, Washington, DC 20201.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the first day an update from HHS has been scheduled on the implementation of the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Committee will be briefed by the Director of the National Center for Health Statistics on several health data activities. In addition, there may be a discussion of a possible draft letter to the HHS Secretary regarding digital signatures. The Committee will also discuss action items reported in the summary from its 50th Anniversary Symposium held earlier in the year. There will also be a report on two recent meetings of the World Health Organization's (WHO) collaborating Center for the Classification of Diseases. A panel discussion has been scheduled on HIPAA implementation issues. The first day will end with breakout sessions for subcommittees and workgroups. Day two will also begin with breakout sessions and then the full committee will be briefed on selected HHS data policy initiatives and will hear an analysis of State privacy laws. The afternoon session will be devoted to hearing reports from the subcommittees and workgroups and the setting of future agendas.

Notice: In the interest of security, HHS has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Persons without a government identification card may need to have the guard call for an escort to the meeting.

Contact Person for Core Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS website: http://www.ncvhs.hhs.gov/, where further information including an agenda will be posted when available.

Dated: October 18, 2000.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 00–27462 Filed 10–25–00; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1268]

Agency Information Collection Activities; Announcement of OMB Approval; Food Additives and Food Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Additives and Food Additive Petitions'' 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 3, 2000 (65 FR 47736), 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 0910–0016. The approval expires on October 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: October 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–27546 Filed 10–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1373]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reporting and Recordkeeping Requirements for Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 27, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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 compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting and Recordkeeping Requirements for Mammography Facilities—21 CFR Part 900 (OMB Control Number 0910–0309)—Extension

Public Law 102–539, the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b) as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998 (Public Law 105–248) establishes the authority for a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. MQSRA extended the life of the MQSA program for 4 years from its original expiration date of 1998 until 2002, and also modified some of the provisions. The most significant modification from a report and recordkeeping viewpoint under 21 CFR 900.12(c)(2) was that mammography facilities were required to send a lay summary of each examination to the patient.

FDA, under this regulation, collects information from accreditation bodies and mammography facilities by requiring each accreditation body to submit an application for approval and to establish a quality assurance program. On the basis of accreditation, facilities are certified by FDA and must prominently display their certificate. FDA uses the information to ensure that private, nonprofit organizations or State agencies meet the standards established by FDA for accreditation bodies to accredit facilities that provide mammography services. Information collected from mammography facilities has also been used to ensure that the personnel, equipment, and quality systems has and continues to meet the regulations under MQSA and will be used by patients to manage their health care properly. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level. The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

In the **Federal Register** of July 17, 2000 (65 FR 44061), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
900.3	6	1	6	60	360		
900.3(b)(3)	10	1	10	60	600	$50	
900.3(c)	4	0.14	0.56	15	8.4		
900.3(e)	1	0.2	0.2	1	0.2		
900.3(f)(2)	1	0.2	0.2	1	0.2		
900.4(c)	834	1	834	1	834		
900.4(e)	10,000	1	10,000	8	80,000		
900.4(f)	1,000	1	1,000	14.5	14,500		
900.4(h)	6	1	750	6	4,500		
900.4(i)(2)	1	1	1	1	1		
900.6(c)(1)	1	1	1	1	1		
900.11(b)(2)	25	1	25	2	50		
900.11(b)(3)	5	1	5	0.5	2.5		
900.11(c)	10,000	0.0050	50	20	1,000		$1,000
900.12(c)(2)	9,800	4,080	39,984,000	5 minutes	3,332,000		
900.12(j)(1)	10	1	10	1	10		
900.15(d)(3)(ii)	10,000	0.0020	20	2	40		$100
900.18(c)	10,000	0.0005	6	2	12		$60
900.18(e)	10	0.1000	1	1	1		$10
Total					3,434,010	$50,	$1,170

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating and Maintenance Costs
900.3(f)(1)	10	130	1,300	200	2,000	
900.4(g)	10,000	1	10,000	1	10,000	
900.11(b)(1)	1,000	1	1,000	1	1,000	
900.12(c)(4)	10,000	1	10,000	1	10,000	
900.12(e)(13)	6,000	52	312,000	0.125	39,000	
900.12(f)	10,000	1	10,000	1	10,000	
900.12(h)	10,000	2	20,000	0.5	10,000	$20,000
Total					82,000	$20,000

[1]There are no capital costs associated with this collection of information.

All costs of implementing requirements for certification of mammography facilities will be borne by accreditation bodies; the incremental costs that accreditation bodies will face are not expected to be significant. The collection's burden is based upon the estimated number of summaries received by FDA, which in turn is based

on the estimated number of examinations expected to be performed in a given year. If mammography examinations increase in number in subsequent years, which is expected for at least the foreseeable future, the annual burden and costs to meet this requirement will increase.

Included in the burden estimate is the FDA estimate for mammography lay summaries, which is the practice of notifying the patient in layman's terms of the results of the patient's mammography examination. FDA estimates that there are 9,800 facilities performing mammography in the United States. FDA also estimates that those facilities perform a total of 40 million mammography examinations in a year. In 90 percent of these cases, the notification to the patient can be established by a brief standardized letter to the patient. FDA estimates that preparing and sending this letter will take approximately 5 minutes. In the 10 percent of the cases in which there is a finding of ''Suspicious'' or ''Highly suggestive of malignancy,'' the facility is required to make reasonable attempts to ensure that the results are communicated to the patients as soon as possible. FDA believes that this requirement can be met by a 5-minute call from the health professional to the patient.

Dated: October 19, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–27453 Filed 10–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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). The meeting will be open to the public.

Name of Committee: Biological Response Modifiers 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 November 16 and 17, 2000, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 16 and 17, 2000, the committee will meet to discuss the following issues related to gene therapy clinical trials: (1) Product characterization, (2) preclinical models, and (3) long term followup.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 9, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on November 16, 2000, and from 9 a.m. to 9:30 a.m. on November 17, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–27455 Filed 10–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration; 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). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration.

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 November 17, 2000, 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, CDER Advisory Committee Meeting Room, 5630 Fishers Lane, Rockville, MD 20857.

Contact Person: Susan Mackie Bond, Office of Science Coordination and Communication (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12603. Please call the Information Line for up-to-date information on this meeting.

Agenda: The board will meet to hear and to discuss the following issues: (1) Emerging science issues at FDA, (2) strategies for maintaining quality of science at FDA, and (3) programmatic peer review.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 7, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 7, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 18, 2000.

Linda S. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–27456 Filed 10–25–00; 8:45 am]

BILLING CODE 4160–01–F