The issues to be considered at the hearing are:

• Whether California has demonstrated that the proposed payments to providers were sufficient to enlist enough providers so that care and services were available under the State's Medicaid plan at least to the extent that such care and services are available to the general population in the geographic area as required by section 1902(a)(30)(A) of the Social Security Act.

• Whether the application of the payment rates under the SPAs retroactively, based on the proposed effective date, would be consistent with that requirement under section 1902(a)(30)(A) of the Act.

Section 1116 of the Act and Federal regulations at 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. CMS is required to publish a copy of the notice to a State Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to California announcing an administrative hearing to reconsider the disapproval of its SPAs reads as follows:

Mr. Toby Douglas, Chief Deputy Director
Health Care Programs
Department of Health Care Services
1501 Capitol Avenue, 6th Floor
MS 0002
Sacramento, CA 95814

Dear Mr. Douglas:

I am responding to your request for reconsideration of the decision to disapprove the California State Plan Amendments (SPAs) 08–009A; 08–009B1; 08–009B2; 08–009D which were submitted on September 30, 2008, and 08–019 which was submitted on December 31, 2009, and disapproved on November 18, 2010. The SPAs proposed to reduce the reimbursement rates for certain services furnished under the approved State plan.

The issues to be considered at the hearing are:

• Whether California has demonstrated that the SPAs assured that the proposed payments to providers would be sufficient to enlist enough providers so that care and services were available under the State's Medicaid plan at least to the extent that such care and services are available to the general population in the geographic area as required by section 1902(a)(30)(A) of the Social Security Act.

• Whether the application of the payment rates under the SPAs retroactively, based on the proposed effective date, would be consistent with that requirement under section 1902(a)(30)(A) of the Act.

In reviewing this issue, we note that, when the SPAs were initially submitted, the State did not provide any information concerning the impact of the proposed reimbursement reductions on beneficiary access to services, even though available national data indicated that this may be an issue for California.

In Requests for Additional Information (RAI) for SPAs TN 08–009A, TN 08–009B1, TN 08–009D (sent to the State in December 2008) and 08–019 (sent to the State in March 2009), CMS requested information about beneficiary access to services, but California never responded. As indicated in a January 2, 2001, letter to State Medicaid Directors, to the extent that responses to such RAIs are not received within 90 days, CMS may initiate disapproval action. In this instance, in addition, CMS was concerned that, given the time that had elapsed since these SPAs had been submitted but were not implemented, the cumulative effect of a retroactively effective approval of these reimbursement reductions exacerbate beneficiary access concerns.

I am scheduling a hearing on your request for reconsideration to be held on February 10, 2011, at the CMS San Francisco Regional Office, 90 7th Street, #5–300 (5W), San Francisco, California 94103–6706, in order to reconsider the decision to disapprove SPAs 08–009A; 08–009B1; 08–009B2; 08–009D; and 08–019. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by Federal regulations at 42 CFR Part 430.

I am designating Mr. Benjamin Cohen as the presiding officer. If these arrangements are not acceptable, please contact the presiding officer at (410) 786–3169. To facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled, and to provide names of the individuals who will represent the State at the hearing.

Sincerely,

Donald M. Berwick, M.D.

Section 1116 of the Social Security Act (42 U.S.C. section 1316; 42 CFR section 430.18)

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: December 15, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–32007 Filed 12–20–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Advisory Committees; Tentative Schedule of Meetings for 2011

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2011. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the Agency to publish an annual tentative schedule of its meetings in the **Federal Register**. This publication implements the IOM's recommendation.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5290, Silver Spring, MD 20993–0002, 301–796–8220.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report in 1992, one of the IOM's recommendations was for FDA to adopt a policy of publishing an advance yearly schedule of its upcoming public

advisory committee meetings in the **Federal Register**; FDA has implemented this recommendation. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. Because the schedule is tentative, amendments to this notice will not be published in the **Federal Register**. However, changes to the schedule will be posted on the FDA advisory committees' Internet site located at *http://www.fda.gov/AdvisoryCommittees/default.htm*. FDA will continue to publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, to announce the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for 2011.

TABLE 1

Committee name	Tentative date(s) of meeting(s)
OFFICE OF THE COMMISSIONER	
Pediatric Advisory Committee	March 21, June 21–22, December 5–6.
Risk Communication Advisory Committee	February 10–11, May 5–6, August 15–16, November 17–18.
Science Board to the Food and Drug Administration	February 25, May 20, August 19, November 10.
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
Allergenic Products Advisory Committee	May 12.
Blood Products Advisory Committee	April 28–29, August 3–4, December 1–2.
Cellular, Tissue and Gene Therapies Advisory Committee	February 10, September 22–23.
Transmissible Spongiform Encephalopathies Advisory Committee	Date(s), if needed, to be determined.
Vaccines and Related Biological Products Advisory Committee	February 24–25, May 18–19, September 20–21, November 16–17.
CENTER FOR DRUG EVALUATION AND RESEARCH	
Anesthetic and Life Support Drugs Advisory Committee	March 10.
Anti-Infective Drugs Advisory Committee	April date(s), if needed, to be determined.
Antiviral Drugs Advisory Committee	April 27–29.
Arthritis Advisory Committee	March 15–16, May 3.
Cardiovascular and Renal Drugs Advisory Committee	March 31, April 1, July 26–27, October 20–21, December 13–14.
Dermatologic and Ophthalmic Drugs Advisory Committee	April 13.
Drug Safety and Risk Management Advisory Committee	Date(s), if needed, to be determined.
Endocrinologic and Metabolic Drugs Advisory Committee	March 24.
Gastrointestinal Drugs Advisory Committee	January 12, March 8, May date(s), if needed, to be determined.
Nonprescription Drugs Advisory Committee	February 23–24.
Oncologic Drugs Advisory Committee	February 8–9, March 29–30, June 28–29, July 13–14, September 14–15, December 7–8.
Peripheral and Central Nervous System Drugs Advisory Committee	January 20–21, March 10.
Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.	March 2.
Psychopharmacologic Drugs Advisory Committee	Date(s), if needed, to be determined.
Pulmonary-Allergy Drugs Advisory Committee	March 8.
Advisory Committee for Reproductive Health Drugs	March 4, April and May date(s), if needed, to be determined.
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	
Medical Devices Advisory Committee (Comprised of 18 Panels)	
Anesthesiology and Respiratory Therapy Devices Panel	April 15.
Circulatory System Devices Panel	January 25–26, February 24–25, March 24–25, April 28–29, December 8–9.
Clinical Chemistry and Clinical Toxicology Devices Panel	November 9.
Dental Products Panel	April 12–13, September 8–9.
Ear, Nose, and Throat Devices Panel	September 28–29.
Gastroenterology-Urology Devices Panel	January 20–21, April 21–22, July 14–15, October 27–28.
General and Plastic Surgery Devices Panel	February 24–25, May 12–13, August 11–12, November 17–18.
General Hospital and Personal Use Devices Panel	July 29.
Hematology and Pathology Devices Panel	March 24–25, June 9–10, September 15–16, December 15–16.
Immunology Devices Panel	March 31, June 30, September 29, December 1.
Medical Devices Dispute Resolution Panel	April 8.
Microbiology Devices Panel	October 13.
Molecular and Clinical Genetics Panel	March 3–4.
Neurological Devices Panel	January 27–28, March 17.
Obstetrics and Gynecology Devices Panel	May 19–20, September 22–23.
Ophthalmic Devices Panel	February 18.
Orthopedic and Rehabilitation Devices Panel	April 26–27, July 8.
Radiological Devices Panel	June 17, October 27–28.
National Mammography Quality Assurance Advisory Committee	May 6, August 9.
Technical Electronic Product Radiation Safety Standards Committee	May 25.

TABLE 1—Continued

Committee name	Tentative date(s) of meeting(s)
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	
Food Advisory Committee	March 30–31.
CENTER FOR TOBACCO PRODUCTS	
Tobacco Products Scientific Advisory Committee	January 10–11, March 17–18, May, July, September, and November date(s), if needed, to be determined.
CENTER FOR VETERINARY MEDICINE	
Veterinary Medicine Advisory Committee	April 11, September 12.
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	
Science Advisory Board	November 9–10.

Dated: December 16, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–31961 Filed 12–20–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0626]

Abbott Laboratories, Inc.; Withdrawal of Approval of a New Drug Application for MERIDIA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for MERIDIA (sibutramine hydrochloride (HCl)) oral capsules held by Abbott Laboratories, Inc. (Abbott), 100 Abbott Park Rd., Abbott Park, IL 60064. Abbott has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective December 21, 2010.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: On October 7, 2010, FDA requested that Abbott voluntarily withdraw MERIDIA (sibutramine HCl) oral capsules from the market, based on FDA's recent analysis of clinical trial data from the Sibutramine Cardiovascular Outcomes Trial (SCOUT) that indicated that MERIDIA poses an increased risk of heart attack and stroke. In a letter dated October 12, 2010, Abbott requested that FDA withdraw approval of NDA 20–632 for MERIDIA (sibutramine HCl) oral capsules under § 314.150(d) (21 CFR 314.150(d)). In that letter, Abbott also waived its opportunity for a hearing, provided under § 314.150(a). In FDA's acknowledgment letter of November 1, 2010, the agency stated that based on the review of the SCOUT data and the assessment of the September 15, 2010, meeting of FDA's Endocrinologic and Metabolic Drugs Advisory Committee at which the SCOUT data were reviewed, we find the benefits of MERIDIA (sibutramine HCl) oral capsules, indicated for the management of obesity, including weight loss and maintenance of weight loss, no longer outweigh the risks in any identifiable patient population. FDA also acknowledged that Abbott waived its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated by the Commissioner of Food and Drugs to the Director, Center for Drug Evaluation and Research, approval of NDA 20–632, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: December 6, 2010.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2010–31986 Filed 12–20–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

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

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Unsolicited Multi-Project (P01) Grant Applications.

Date: January 12, 2011.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call.)

Contact Person: Roberta Binder, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, Room 3130, Bethesda, MD 20892–7616. 301–496–7966. *rbinder@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)