Name of Committee: Orthopaedic and Rehabilitation 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 November 5, 1999, 8:30 a.m. to 5:30 p.m. (this notice is for the second day of a 2-day meeting).

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

Contact Person: William Freas or Sheila D. Langford, 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 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss postmarketing studies of Genzyme Corporation's Carticel (autologous chondrocytes manipulated ex-vivo for structural repair) indicated for treatment and repair of clinically significant, articular cartilage defects in the knee. The discussion will focus on issues specific to these studies and on more general ones related to the feasibility of randomized controlled trials in the field of orthopaedics.

Procedure: On November 5, 1999, from 8:30 a.m. to 5:30 p.m., the meeting is open to the public. 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 1, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. and between approximately 1:00 p.m and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 1, 1999, 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 12, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–27154 Filed 10–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

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: Orthopaedic and Rehabilitation 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 November 4, 1999, 9 a.m. to 4:30 p.m.

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

Contact Person: Hany W. Demian, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 4, 1999, the committee will discuss and make recommendations on the reclassification of constrained total hip arthroplasty devices. The committee will also discuss the development of computer controlled surgical systems designed for use in orthopaedic procedures.

Procedure: On November 4, 1999, from 9 a.m. to 3 p.m., the meeting is open to the public. 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 October 29, 1999. On November 4, 1999, oral presentations from the public regarding the reclassification of constrained total hip arthroplasy devices and the development of computer controlled surgical systems designed for use in orthopaedic procedures will be scheduled between approximately 11 a.m. and 11:30 a.m. and between approximately 2:30 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by October 29, 1999, 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.

Closed Presentation of Data: On November 4, 1999, from 3 p.m. to 4 p.m., the meeting will be closed to permit a sponsor to present to the committee trade secret and/or confidential commercial information on a clinical study design. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Closed Committee Deliberations: On November 4, 1999, from 4 p.m. to 4:30 p.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

Dated: October 12, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–27158 Filed 10–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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). Portions of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products 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 4, 1999, 8 a.m. to 6

p.m., and on November 5, 1999, 8 a.m. to 4 p.m.

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

Contact Person: Nancy T. Cherry or Denise H. Royster, 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 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 4, 1999, the committee will discuss: (1) Ways to demonstrate attenuation of chimeric strains of Cytomegaloviral candidate vaccines to support proceeding into clinical trials, and (2) the safety data following a fifth successive dose of DTaP (Tripedia) manufactured by Connaught Laboratories, Inc. On November 5, 1999, the product license application for Wyeth Lederle Vaccines and Pediatrics' Pneumococcal 7–Valent Conjugate Vaccine (Diphtheria CRM197 protein) will be discussed for use in infants and young children. The committee will be asked to consider the safety and efficacy of this vaccine against prevention of invasive disease (bacteremia and meningitis) caused by *Streptococcus pneumoniae* (pneumococcus).

Procedure: On November 4, 1999, from 9 a.m. to 1:30 p.m., and from 2 p.m. to 6 p.m., and on November 5, 1999, from 9 a.m. to 4 p.m., the meeting is open to the public. 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 October 28, 1999. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 11:45 a.m., and between approximately 3:30 p.m. and 3:45 p.m. on November 4, 1999. On November 5, 1999, the oral presentations will be scheduled from approximately 1:30 p.m. to 1:45 p.m., and from approximately 3:15 p.m. to 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 28, 1999, 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 presentations.

Closed Committee Deliberations: On November 4, 1999, from 8 a.m. to 9 a.m., and from approximately 1:30 p.m. to 2 p.m., and on November 5, 1999, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). These portions of the meeting will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications.

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

Dated: October 12, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–27157 Filed 10–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–5001–N]

Medicare Program; Establishment of the Health Care Financing Administration's Management Advisory Committee

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: In accordance with Public Law 92–463, the Federal Advisory Committee Act (FACA), we are announcing the establishment of the Management Advisory Committee (MAC). The Secretary signed the charter establishing the MAC on September 24, 1999. The MAC will terminate on September 24, 2001, unless we formally determine that continuance is in the public interest.

The MAC will advise and make recommendations to us on issues of management and leadership practices, purchasing strategies, and ways to improve our overall performance, accountability, and operations. The MAC will not make recommendations regarding payment or coverage policy.

ADDRESSES: A request for a copy of the charter for the MAC should be submitted to Corinne Marvin, Office of Strategic Planning, Health Care Financing Administration, 7500 Security Boulevard, C3–20–11, Baltimore, Maryland 21244–1850, (410) 786–4681, or by e-mail to mgtadvbrd@hcfa.gov.

FOR FURTHER INFORMATION CONTACT: Corinne Marvin, (410) 786–4681.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

The Management Advisory Committee (MAC) is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formulation and use of advisory committees. We have found that the MAC is necessary and in the public interest.

The MAC consists of 11 appointed members from among nationally recognized authorities in academia, public and private sector health purchasing organizations, private consultants, and private sector businesses.

We will appoint members to a term of between 1 and 4 years, with 3 and 4 year appointments contingent on our decision that it is in the public interest to continue the MAC beyond the initial 2-year term described in the Charter. The MAC will provide recommendations to assist us in improving our management. The MAC will issue a report to us at the end of the 2-year charter on its findings and recommendations.

Authority: (5 U.S.C. Appendix 2).

(Catalog of Federal Domestic Assistance Program No. 99.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 13, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–27251 Filed 10–18–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Notice of Hearing: Reconsideration of Disapproval of New Mexico Children's Health Insurance Program State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on December 8, 1999; at 10:00 a.m.; Eighth Floor; Conference Room 820; 1301 Young Street; Dallas, Texas 75202 to reconsider our decision to disapprove New Mexico SPA.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by November 3, 1999.