(nevirapine), Valtrex (valacyclovir), Zmax (azithromycin), Rotarix (rotavirus vaccine, live, oral), Kinrix (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine), Pentacel [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate Vaccine), and Daptacel [Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed vaccine]. The committee will also receive an update on Topical Calcineurin Inhibitors: Elidel (pimecrolimus) and Protopic (tacrolimus). Also, the committee will receive a brief followup on the FDA Early Communication about reports of liver-related adverse events in patients taking orlistat (marketed as Alli and Xenical).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

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 on or before March 8, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before February 28, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 1, 2010.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Doreen Kezer, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–3024 Filed 2–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Times and Dates: 12 p.m.–5 p.m., March 15, 2010. 8:30 a.m.–5 p.m., March 16, 2010. 8:30 a.m.–3 p.m., March 17, 2010.

Place: Crowne Plaza Atlanta Perimeter at Ravinia, 4355 Ashford Dunwoody Road, Atlanta, GA 30346. Telephone: 770–395–7700.

Status: Open to the public, limited only by the number of seats available.

Purpose: The committee is charged with advising the Secretary, Department of Health and Human Services, and the Director, CDC, regarding the early detection and control of breast and cervical cancer. The committee makes recommendations regarding national program goals and objectives; implementation strategies; and program priorities including surveillance, epidemiologic investigations, education and training, information dissemination, professional interactions and collaborations, and policy.

Matters To Be Discussed: The agenda will include discussion and review of U.S. Preventive Services Task Force guidelines for breast and cervical cancer screening; Impact of the revised clinical screening recommendations for both breast and cervical cancer on the National Breast and Cervical Cancer Early Detection Program; Discussion of what, if any, modifications should be made to the NBCCEDP’s current screening policies based on revised recommendations. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Dr. Chastity Walker, Designated Federal Officer, BCCEDCAC, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop K–57, Chamblee, Georgia 30316. Telephone: 770–488–3013.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.


Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–3143 Filed 2–17–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices 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: Circulatory System 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 March 18 and 19, 2010, from 8 a.m. to 6 p.m.

Location: College Park Holiday Inn, Grand Ballroom, 10000 Baltimore Ave., College Park, MD.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD.
The aforementioned meeting:

Agenda: On March 18, 2010, the committee will discuss, make recommendations, and vote on the premarket approval application (PMA) for the Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) sponsored by Boston Scientific. The sponsor is seeking expanded indications for the CRT-Ds to include patients with low left ventricular ejection fraction (≤30%) and wide QRS (≥130 ms) who are NYHA Class II (ischemic or non-ischemic etiology) or NYHA Class I (ischemic etiology).

On March 19, 2010, the committee will discuss, make recommendations and vote on a PMA for the REVO MRI Pacemaker System sponsored by Medtronic. The REVO MRI Pacing System is a pacemaker (with a standard pacing indication) that has been specifically designed to be safe for the MRI environment under certain MR scanning conditions.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm, scroll down to the appropriate advisory committee link.

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 on or before March 11, 2010. Oral presentations from the public will be scheduled immediately following lunch. Those desiring to make formal oral presentations should notify the contact person 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 on or before March 3, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 4, 2010.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under 5 U.S.C. app. 2.


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Board of Scientific Counselors, Coordinating Center for Infectious Diseases, (BSC, CCID)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 10 a.m.–11 a.m., March 2, 2010.
Place: Teleconference.
Status: Open to the public, the toll free dial in number is 1–866–880–0098 with a pass code of 9887280.
Purpose: The BSC, CCID shall advise the Secretary, HHS, and the Director, CDC concerning strategies and goals for the programs and research within the national centers; will administer and oversee peer review of scientific programs; and monitor the overall strategic direction and focus of the national centers.

Matters To Be Discussed: Agenda items will include:
1. Update from Dr. Khabbaz.
2. Update on H1N1 response.