Application No.	Drug	Applicant
NDA 018168	DEMULEN 1/35–21 (ethinyl estradiol; ethynodiol diacetate) Tablet, 0.035 mg; 1 mg.	Do.
NDA 019190	TRIPHASIL–28 (ethinyl estradiol; levonorgestrel) Tablet, 0.03 mg, 0.04 mg, 0.03 mg; 0.05 mg, 0.075 mg, 0.125 mg.	Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 019192	TRIPHASIL–21 (ethinyl estradiol; levonorgestrel) Tablet, 0.03 mg, 0.04 mg, 0.03 mg; 0.05 mg, 0.075 mg, 0.125 mg.	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31146 Filed 12–2–11; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0176]

SEDASYS Computer-Assisted Personalized Sedation System; Ethicon Endo-Surgery, Incorporated's Petition for Review of the Food and Drug Administration's Denial of Premarket Approval; Notice of Cancellation of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Medical Devices Dispute Resolution Panel scheduled for December 14, 2011, is cancelled. This meeting was announced in the **Federal Register** of November 21, 2011 (76 FR 71980).

FOR FURTHER INFORMATION CONTACT: Nancy Braier, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 5454, Silver Spring, MD 20993–0002, (301) 796–5676, FAX: (301) 847–8510, email: *nancy.braier@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The meeting of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee scheduled for December 14, 2011, is cancelled. On December 14, 2011, this advisory committee was slated to discuss the Center for Devices and Radiological Health's (CDRH's) denial of a premarket approval application (PMA) for the SEDASYS computer-assisted personalized sedation system (SEDASYS) submitted by Ethicon Endo-Surgery Inc. (EES), the sponsor for SEDASYS. This meeting has been cancelled because EES has withdrawn its petition for review of this denial.

On February 26, 2010, CDRH issued a letter to EES indicating that PMA P080009 for SEDASYS was not approvable under § 814.44(f) (21 CFR 814.44(f)) because CDRH concluded that the data and information offered in support of the PMA did not provide a reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling, as required by section 515(d)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(2)(A)).

On March 25, 2010, EES requested review of the not approvable letter. Submitted in the form of a petition for reconsideration under 21 CFR 10.33 (see 21 CFR 814.44(f)(2)), EES's petition stated that, in accordance with § 814.44(f), EES considered the not approvable letter to be a denial of approval of PMA P080009 under § 814.45 (21 CFR 814.45). In accordance with section 515(d)(4) of the FD&C Act, EES requested review of this denial under section 515(g)(2) of the FD&C Act. Subsequently, on October 26, 2010, CDRH issued an order denying approval of the SEDASYS PMA (Denial Order), as required by § 814.45(e)(3). On November 5, 2010, in accordance with section 515(g)(2) of the FD&C Act, FDA granted EES's petition for review of the Denial Order.

FDA's Office of the Commissioner (OC) referred PMA P080009 and the basis for CDRH's Denial Order to the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee, an advisory committee of experts established, in part, to receive referrals of petitions for advisory committee review under section 515(g)(2)(B) of the FD&C Act. (See 76 FR 15321, March 21, 2011.) In the **Federal Register** of November 21, 2011, FDA announced that this advisory committee was scheduled to meet to discuss the clinical and scientific issues raised by CDRH's Denial Order on December 14, 2011.

By letter dated November 28, 2011, EES notified OC that EES ''withdraws its request for administrative review'' of that order ''through an independent advisory committee under Section 515(g)(2) of the Federal Food, Drug, and Cosmetic Act.'' Because EES has withdrawn its petition for review of CDRH's denial of approval of the SEDASYS PMA, OC regards the matter it initiated closed and is, accordingly, canceling the previously mentioned meeting of the Medical Devices Dispute Resolution Panel scheduled for December 14, 2011.

Dated: November 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31105 Filed 12–2–11; 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 Meeting

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

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: AIDS Research Advisory Committee, NIAID, AIDS Vaccine Research Subcommittee.

Date: January 31–February 1, 2012.

Time: 8:30 a.m. to 5 p.m.

Agenda: The AVRS will meet with the NIAID-sponsored Strategic Working Group (SWG). Presentations and discussion of current and future plans of the HIV Vaccine Trials Network (HVTN).

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: James A. Bradac, Ph.D., Program Official, Preclinical Research and Development Branch, Division of AIDS, Room 5116, National Institutes of Health/NIAID, 6700B Rockledge Drive, Bethesda, MD 20892–7628, (301) 435–3754, *jbradac@mail.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)

Dated: November 29, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–31154 Filed 12–2–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering; NACBIB January 2012.

Date: January 20, 2012.

Open: 9 a.m. to 1 p.m.

Agenda: Report from the Institute Director, other Institute Staff and presentation of working group reports.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room, 2nd Level, Bethesda, MD 20817.

Closed: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room, 2nd Level, Bethesda, MD 20817.

Contact Person: Anthony Demsey, Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 241, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nibib1.nih.gov/about/NACBIB/NACBIB.htm*, where an agenda and any additional information for the meeting will be posted when available.

Dated: November 29, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–31157 Filed 12–2–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the AIDS Research Advisory Committee, NIAID.

The meetings will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of themeeting.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: January 30, 2012.

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

Agenda: Reports from the Division Director and other staff.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

Contact Person: Rona L. Siskind, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, 6700B Rockledge Drive, Room 4139, Bethesda, MD 20892–7601, (301) 435–3732.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: May 14, 2012.

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

Agenda: Reports from the Division Director and other staff.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

Contact Person: Rona L. Siskind, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, 6700B Rockledge Drive, Room 4139, Bethesda, MD 20892–7601, (301) 435–3732.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: September 24, 2012.

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

Agenda: Reports from the Division Director and other staff.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

Contact Person: Rona L. Siskind, Executive Secretary AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, 6700B Rockledge Drive, Room 4139, Bethesda, MD 20892–7601, (301) 435–3732.

(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)

Dated: November 29, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–31155 Filed 12–2–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, December 5, 2011, 6:30 p.m. to December 6, 2011, 5 p.m., National Institutes of Health, Building