Agenda: On February 9, 2011, the committee will discuss biologics license application (BLA) 125377, with the proposed trade name YERVOY (ipilimumab), submitted by Bristol-Myers Squibb Co. The proposed indication (use) for this product is for the treatment of advanced melanoma in patients who have received prior therapy.

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 January 25, 2011. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. Those individuals interested in making 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 January 14, 2011. 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 January 18, 2011.

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 Nicole Vesely 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).

Dated: December 1, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–30502 Filed 12–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Peripheral and Central Nervous System Drugs 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: Peripheral and Central Nervous System Drugs 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 January 20, 2011, from 8 a.m. to 5 p.m. and on January 21, 2011, from 8 a.m. to 12 p.m.

Location: FDA White Oak Campus, Building 31 Conference Center, the Great Room (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX 301–847–8533, e-mail: *diem.ngo@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 20, 2011, the committee will discuss new drug application (NDA) 202–008, florbetapir F 18 injection, sponsored by Avid Radiopharmaceuticals, Inc., proposed for use in positron emission tomography (PET) imaging of β-amyloid (beta-amyloid) aggregates in the brain to help rule out Alzheimer's disease.

On January 21, 2011, the committee will discuss NDA 201–277, gadobutrol injection, sponsored by Bayer HealthCare Pharmaceuticals, proposed for use in diagnostic magnetic resonance imaging (MRI) in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity (abnormal blood supply and circulation) of the central nervous system. The BBB is an area consisting of specialized cells that restrict passage of certain molecules from the bloodstream into the brain.

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 January 5, 2011.

Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on January 20, 2011, and between approximately 10 a.m. and 11 a.m. on January 21, 2011. Those individuals interested in making 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 December 27, 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 December 28, 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 Diem-Kieu Ngo 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).

Dated: December 1, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–30501 Filed 12–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–N–0163; Formerly Docket No. 2000N–1219]

Reclassification of Category IIIA Biological Products, Bacterial Vaccines and Related Biological Products; Implementation of Efficacy Review; Final Order; and Delmont Laboratories, Inc.: Denial of Request for a Hearing, and Revocation of License

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order pursuant to the reclassification procedures under the biologics regulations; denying the request by Delmont Laboratories, Inc. (Delmont), for a hearing on FDA's proposal to revoke Delmont's license based on the proposed reclassification of its product, Polyvalent Bacterial Antigens with "No U.S. Standard of Potency," Staphage Lysate® (SPL) (hereinafter referred to as SPL) into Category II (unsafe, ineffective, or misbranded); and revoking Delmont's U.S. License No. 299. The final order finalizes the proposed order published in the **Federal Register** of May 15, 2000 (65 FR 31003) (May 2000 proposal), to reclassify Category IIIA bacterial vaccines and bacterial antigens into Category I or Category II.

DATES: The final order reclassifying Delmont's SPL into Category II, and Sanofi Pasteur Inc.'s (Sanofi's) Tetanus Toxoid Adsorbed and Tetanus and Diphtheria Toxoids Adsorbed For Adult Use (DECAVAC™) into Category I for both primary immunization and booster use is effective December 6, 2010. The revocation of Delmont's license (U.S. License No. 299) is effective December 6, 2010.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background on the Efficacy Review Process

In the **Federal Register** of February 13, 1973 (38 FR 4319), FDA issued procedures for the review by independent advisory panels of the safety, effectiveness, and labeling of biological products licensed before July 1, 1972. These procedures were later codified in § 601.25 (21 CFR 601.25) (38 FR 32048 at 32052, November 20, 1973). Under § 601.25, FDA assigned responsibility for the initial review of each of the biological product categories to a separate independent advisory panel consisting of qualified experts. Each panel was charged with preparing for the Commissioner of Food and Drugs an advisory report which was to: (1) Evaluate the safety and effectiveness of the biological products for which a license had been issued; (2) review their labeling; and (3) identify the biological products that are safe, effective, and not misbranded. Each advisory panel report was also to include recommendations classifying the products reviewed into one of three categories.

- Category I, designating those biological products determined by the panel to be safe, effective, and not misbranded.
- Category II, designating those biological products determined by the panel to be unsafe, ineffective, or misbranded.
- Category III, designating those biological products determined by the panel not to fall within either Category I or Category II on the basis of the panel's conclusion that the available data were insufficient to classify such biological products, and for which further testing was therefore required. Category III products were assigned to one of two subcategories. Category IIIA products were those that would be permitted to remain on the market pending the completion of further studies. Category IIIB products were those for which the panel recommended license revocation on the basis of the panel's assessment of potential risks and benefits.

In accordance with § 601.25, after reviewing the conclusions and recommendations of the review panels, FDA would publish in the **Federal Register** a proposed order containing: (1) A statement designating the biological products reviewed into Categories I, II, IIIA or IIIB; (2) a description of the testing necessary for Category IIIA biological products; and (3) the complete panel report. Under the proposed order, FDA would propose to revoke the licenses of those products designated into Category II and Category IIIB. After reviewing public comments, FDA would publish a final order on the matters covered in the proposed order.

Two original advisory panels reviewed the four Category IIIA products that are the subject of this final order. The advisory panel for Bacterial Vaccines and Bacterial Antigens with