**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 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.

**Fees and Registration:**

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.**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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, Polyclonal Bacterial Antigens with “No U.S. Standard of Potency.” Staphage Lysate® (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 Diphteria Toxoids Adsorbed For Adult Use (DECAVACTM) 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.


SUPPLEMENTAL 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