reclassification, and has availed itself of two opportunities to comment on and object to FDA’s proposal: (1) On August 9, 2000, in response to FDA’s May 2000 proposal, and (2) on April 28, 2003, in response to FDA’s NOOH (68 FR 8908). FDA has not deprived Delmont of fair notice, nor has FDA precluded Delmont from seeking judicial review.

D. Denial of Hearing Request
For the reasons stated previously in this document, the Commissioner of Food and Drugs (Commissioner) determines that Delmont has failed to raise a genuine and substantial issue of fact to justify a hearing on the proposed revocation of U.S. License No. 299 issued to Delmont Laboratories, Inc. for Polyvalent Bacterial Antigens with “No U.S. Standard of Potency” (Staphage Lysate®) (SPL).

VI. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

2. Fujino, Ryuichi; Yuji Sugisaki; Junko Nakagawa; Masana Komatsu; and Hachihiko Hirayama, “Chronic Toxicity Test of SPL in Rats,” Fujizoki Pharmaceutical Co., Ltd., Shinjuku-ku, Tokyo.
5. “Effect of SPL on the Development of Skin Lesion in Mice after Inoculation with Herpes Simplex Virus,” Department of Microbiology, School of Medicine, Kyushu University, Fukuoka, Japan.
6. “Chemotactic Accumulation of Macrophages in the Peritoneal Cavity after Inoculation of SPL and their Antitumor Activity,” Department of Microbiology, School of Medicine, Kyushu University, Fukuoka, Japan.
10. Azuma, C.; Y. Tokuda; and T. Shibata, “Immunopotentiator Activity of Staphage Lysate (Mudd),” Department of Dermatology, Tokyo College of Medicine, Tokyo.
11. Tsuda, Shingo and Kikuo Minami, “Immunochemotherapy for Infections—With Particular Reference to Staphage Lysate,” Department of Dermatology, Kurume University, School of Medicine, Kurume, Fukuoka Prefecture.

For further information contact: For additional information contact, Lakisha Smith, Executive Secretary, National Advisory Council on Nurse Education and Practice, by e-mail at Lsmith2@hrsa.gov or telephone at (301) 443–5688. A copy of the current committee membership, charter and reports can be obtained by accessing the NACNEP Web site at http://bhpr.hrsa.gov/nursing/nacnep.htm.

SUPPLEMENTARY INFORMATION: Under the authorities that established the NACNEP and the Federal Advisory Committee Act, HRSA is requesting nominations
The Department of Health and Human Services requests a total of eight nominations for members of the NACNEP who represent any of the following groups: Full-time students representing various levels of education in schools of nursing; the general public; practicing professional nurses; leading authorities in the various fields of nursing including advanced practice nurses and associated degree schools of nursing; and representatives of advanced education nursing groups (such as nurse practitioners, nurse midwives, and nurse anesthetists), hospitals, and other institutions and organizations which provide nursing services. The majority of members of the fully constituted Council shall be nurses.

The Department is legally required to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on all HHS Federal advisory committees and, therefore the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in Council composition. Appointment to this Council shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientations, disability, culture, religion or socioeconomic status.

Interested persons may nominate one or more qualified persons for membership. Self-nominations are also accepted. Nominations must be typewritten. The following information should be included in the package of materials submitted for each individual being nominated: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes that qualify the nominee for services in this capacity as described above), a statement that the nominee is willing to serve as a member of the NACNEP and appears to have no conflict of interest that would preclude this Council membership. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, research grants, and/or contracts to permit an evaluation of possible sources of conflicts of interest; and (2) the nominee’s name, address and daytime telephone number; the home/or work address, and telephone number; and finally, the e-mail address of the individual being nominated.

HRSA requests inclusion of a current copy of the nominee’s curriculum vitae and a statement of interest from the nominee which demonstrates experience working with or interest in Title VIII nursing programs; expertise in the field (if applying as a nursing candidate) or understanding of nursing issues (if applying as a general public candidate); and a personal desire to participate on a National Advisory Council. Members will receive a stipend for each day (including travel time) during which they are in attendance at official meetings of the Council, as well as per diem and travel expenses as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service. Qualified candidates will be invited to serve a four-year term.

Dated: November 30, 2010.

Robert Hendricks,
Director, Division of Policy and Information Coordination.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Cancer Immunotherapy.

Date: December 13, 2010.
Time: 12 p.m. to 3 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

(Telephone Conference Call).
Contact Person: Syed M. Quadri, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892. 301-435–1211. quadris@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.


Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Cancer Institute; 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 National Cancer Institute Clinical Trials