

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), and, therefore, denies Delmont's request for a hearing. The Commissioner also determines that Delmont's procedural arguments do not provide a basis for a hearing.

#### IV. Categorization of Products—Final Order

The Commissioner has considered all relevant information regarding the four Category IIIA bacterial vaccines and bacterial antigens subject to reclassification and concludes that FDA's proposal for the reclassification of Category IIIA products into Category I or Category II is adopted as set forth in this section of this document and hereby formally classifies:

Category I—Biological products determined to be safe, effective, and not misbranded, and which may continue to be introduced into interstate commerce. Sanofi Pasteur Inc., U.S. License No.

1725:  
Tetanus Toxoid Adsorbed (primary and booster use), and  
Tetanus and Diphtheria Toxoids Adsorbed For Adult Use (DECAVAC™) (primary and booster use).

Category II—Biological products determined to be unsafe, ineffective, or misbranded, and which may not continue to be introduced into interstate commerce.

Delmont Laboratories Inc., U.S. License No. 299:  
Polyvalent Bacterial Antigens with "No U.S. Standard of Potency" Staphage Lysate® (SPL)

#### V. License Revocation—Final Order

For the reasons set forth in this document, under section 351 of the Public Health Service Act (42 U.S.C. 262) and 21 CFR 601.5(b)(1)(vi), the Commissioner revokes the license (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.

1. Final Report: Addendum to Previous Panel Reports for the Reclassification of Category IIIA Biologics, VRBPAC, 1984.
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.
3. Fujino, Ryuichi; Yuji Sugisaki; Junko Nakagawa; Masana Komatsu; "Acute and Subacute Toxicity Tests of SPL," Fujizoki Pharmaceutical Co., Ltd., Shinjuku-ku, Tokyo.
4. Hirayama, Hachihiko, "Teratogenicity Study of SPL in Rats and Rabbits," Fujizoki Pharmaceutical Co., Ltd., Nerima-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.
7. "S-27: Summary of Results of Tests Conducted at Fuji-Zoki Pharmaceutical Research Division," Fujizoki Pharmaceutical Co., Ltd., Tokyo.
8. Shigeno, N.; T. Mitsuma; and K. Kojima, "Susceptibility of Staphylococcus aureus Clinical Isolates to Gratia Bacteriophage," Junior College of Medical Technology and Nursing affiliated with Niigata University.
9. Mitsuma, T.; N. Shigeno; K. Kojima; and M. Tanaka, "Influence of Staphage Lysate (SPL) on Immune Responses In Vitro," Junior College of Medical Technology and Nursing affiliated with Niigata University and Santo Hospital.
10. Azuma, C.; Y. Tokuda; and T. Shibata, "Immunopotiator 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.
12. Salmon, G.G. and M. Symonds, "Staphage Lysate Therapy in Chronic Staphylococcal Infections," *Journal of*

*the Medical Society of New Jersey*, 60:180-193 (1963).

13. Rank, Dale, "Immune Stimulation Therapy for Inflammatory Disease of the Gut," and "Immune Stimulation for Aphthous (Herpetic) Stomatitis & Rhinitis," (Study Nov. 1975 to Dec. 1977).
14. Rank, Dale, "Immune Stimulation for Aphthous (Herpetic) Stomatitis & Rhinitis," (Jan. 1976 to Jan. 1978).

Dated: November 24, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-30441 Filed 12-3-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Nurse Education and Practice; Notice for Request for Nominations

**SUMMARY:** The Health Resources and Services Administration (HRSA) is requesting nominations to fill eight vacancies on the National Advisory Council on Nurse Education and Practice (NACNEP).

**Authority:** 42 U.S.C. 297t, section 851 of the Public Health Service (PHS) Act, as amended by the Affordable Care Act. The NACNEP is governed by the Federal Advisory Committee Act, Public Law (Pub. L.) 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

**DATES:** The Agency must receive nominations on or before December 22, 2010. Addresses: All nominations are to be submitted either by mail to Lakisha Smith, MPH, Designated Federal Official, NACNEP, Division of Nursing, Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Parklawn Building, Room 9B-45, 5600 Fishers Lane, Rockville, MD 20857 or e-mail at [Lsmith2@hrsa.gov](mailto:Lsmith2@hrsa.gov).

**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](mailto: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

for eight committee members. The NACNEP advises and makes recommendations to the Secretary and Congress on policy matters arising in the administration of Title VIII, including the range of issues relating to the nurse workforce, nursing education and nursing practice improvement. The Advisory Council may make specific recommendations to the Secretary and Congress regarding programs administered by the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration. The Advisory Council provides advice to the Secretary and Congress in preparation of general regulations and with respect to policy matters in the administration of this Title including the range of issues relating to nurse supply, education, and practice improvement. The Advisory Council shall annually prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report describing the activities of the Advisory Council including its findings and recommendations.

The Department of Health and Human Services is requesting 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, higher secondary education and associate 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 nominator'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.*

[FR Doc. 2010-30445 Filed 12-3-10; 8:45 am]

**BILLING CODE 4165-15-P**

## 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](mailto: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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 29, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-30458 Filed 12-3-10; 8:45 am]

**BILLING CODE 4140-01-P**

## 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