

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Advisory Committee. This meeting was originally announced in the **Federal Register** of January 25, 2008 (73 FR 4581). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Carlos Peña, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3340, e-mail: *carlos.Peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 25, 2008, FDA announced that a meeting of the Pediatric Advisory Committee would be held on March 25, 2008. On page 4581, in the third column, the *Agenda* portion of document is changed to read as follows:

Agenda: On March 25, 2008, the Pediatric Advisory Committee will hear and discuss reports by the agency, as mandated in section 17 of the Best Pharmaceuticals for Children Act, on adverse event reports for TOPROL XL (metoprolol), BREVIBLOC (esmolol HCl), LOTENSIN (benazepril), COREG (carvedilol), COLAZAL (balsalazide), ELOXATIN (oxaliplatin), CELEBREX (celecoxib), and SUPRANE (desflurane). The Pediatric Advisory Committee will also hear an update on TRILEPTAL (oxcarbazepine) and the FDA Amendments Act of 2007.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 26, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-4156 Filed 3-4-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Sample Survey of Registered Nurses 2008 (OMB No. 0915-0276)—Reinstatement With Change

The National Sample Survey of Registered Nurses (NSSRN) is carried

out to assist in fulfilling the Congressional mandate of Section 806(f) of the Public Health Service Act (42 U.S.C. 296e) which requires that discipline-specific workforce information and analytical activities are carried out as part of the advanced nursing education, workforce diversity, and basic nursing education and practice programs.

Government agencies, legislative bodies and health professionals used data from previous national sample surveys of registered nurses to inform workforce policies. The information from this survey will continue to serve policy makers, and other consumers. The data collected in this survey will provide information on employment status of registered nurses (RNs), the setting in which they are employed and the proportion of RNs who are employed either full-time and part-time in nursing. The data will also indicate the number of RNs who are employed in jobs unrelated to nursing.

The proposed survey design for the 2008 NSSRN updates that of the previous eight surveys. A probability sample is selected from a sampling frame compiled from files provided by the State Boards of Nursing in the 50 States and the District of Columbia. These files constitute a multiple sampling frame of all RNs licensed in the 50 States and the District of Columbia. Sampling rates are set for each State based on considerations of statistical precision of the estimates and the costs involved in obtaining reliable national and State-level estimates.

Each sampled nurse will be asked to complete a self-administered questionnaire, which includes items on educational background, duties, employment status and setting, geographic mobility, and income. An electronic version was offered in the 2004 survey and will be again considered as a mode for response.

Estimated burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Nursing Survey	39,984	1	39,984	.33	13,195

Written comments and recommendations concerning the proposed information collection should

be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov*

or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: February 28, 2008.

Alexandra Huttinger,
Director, Division of Policy Review and
Coordination.

[FR Doc. E8-4269 Filed 3-4-08; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Eligibility Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Request for Comments on Proposed Changes to the Reimbursement of Travel and Subsistence Expenses Program Eligibility Criteria.

SUMMARY: The Health Resources and Services Administration (HRSA) published the final eligibility guidelines for the Reimbursement of Travel and Subsistence Expense Program in the *Federal Register* on October 5, 2007 (72 FR 57049). The purpose of this notice was to inform the public of the eligibility requirements for participation in the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program. HRSA is requesting public comments concerning recommended change to a specific section of the reimbursement program eligibility guidelines.

DATES: Written comments must be submitted to the office in the address section below by mail or e-mail on or before April 4, 2008.

ADDRESSES: Please send all written comments to James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Room 12C-06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: jburdick@hrsa.gov.

FOR FURTHER INFORMATION CONTACT:

James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: jburdick@hrsa.gov.

SUPPLEMENTARY INFORMATION: In its final program eligibility guidelines, HRSA explained that “[t]he Program will pay for a total of up to five trips; three for

the donor and two for accompanying persons. The accompanying persons need not be the same each trip.” (72 FR 57052). HRSA proposes amending this paragraph to read: “[t]he Program will pay for a total of up to five trips; three for the donor and two for accompanying persons. However, in cases in which the transplant center requests the donor to return to the transplant center for additional visits as a result of donor complications or other health related issues, NLDAC may provide reimbursement for the additional visit(s) for the donor and an accompanying person. The accompanying persons need not be the same in each trip.” The purpose of this proposed change is to accommodate individuals who experience donor complications or other health related issues relating to donation.

HRSA is requesting comments on this specific section.

Dated: February 26, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8-4185 Filed 3-4-08; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

PSM Peptides as Vaccine Targets Against Methicillin-Resistant

Staphylococcus aureus

Description of Technology: Available for licensing and commercial development are compositions and methods for the treatment and inhibition of Methicillin-resistant *Staphylococcus aureus* (MRSA), a dangerous human pathogen. The invention concerns immunogenic peptides that can be used to induce protective immunity against MRSA, including phenol-soluble modulin (PSM) peptides.

In addition to the MRSA infections that occur in immunocompromised patients in hospitals, new MRSA strains have recently emerged that can cause severe infections (such as necrotizing fasciitis) or death in otherwise healthy adults. These strains are increasingly involved in community-associated (CA)-MRSA infections, and can be contracted outside of the health care settings. The incidence of CA-MRSA infections is increasing and the majority of infections in patients reporting to emergency departments in the U.S. is now due to CA-MRSA.

The invention describes a class of secreted staphylococcal peptides with an extraordinary ability to recruit, activate, and subsequently lyse human neutrophils, thus eliminating the main cellular defense against *S. aureus* infection. The peptides are encoded by the PSM gene cluster and include PSM α 1, PSM α 2, PSM α 3, and PSM α 4, all of which activate and subsequently lyse neutrophils. These peptides are produced at especially high levels in CA-MRSA and to a large extent determine their aggressive behavior and ability to cause disease in animal models of infection. Thus, the peptides represent a set of virulence factors of *S. aureus* that account for the enhanced virulence of CA-MRSA. The identification of these peptides enables the production of vaccines and other preventative and/or therapeutic agents for use in subjects infected with MRSA.

Applications: Development of new classes of antibiotics and vaccines against Methicillin-resistant *Staphylococcus aureus* infections.

Inventors: Michael Otto and Rong Wang (NIAID).

Publication: R Wang et al. Identification of novel cytolytic peptides as key virulence determinants for community-associated MRSA. *Nat Med.* 2007. Dec;13(12):1510-1514.

Patent Status: U.S. Provisional Application No. 60/933,573 filed 06 Jun 2007 (HHS Reference No. E-239-2007/0-US-01); U.S. Provisional Application