DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0324]

Withdrawal of Approval of a New Animal Drug Application; Bacitracin Zinc

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) for a bacitracin zinc Type A medicated article. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of this NADA.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–7818; e-mail: *pamela.esposito@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, has requested that FDA withdraw approval of NADA 128–550 for ANCHOR Zinc Bacitracin Type A medicated article because the product is not manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 128–550, and all supplements and amendments thereto, are hereby withdrawn, effective August 28, 2007.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of this NADA.

Dated: August 20, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–16985 Filed 8–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Pretesting of NIAID's HIV Vaccine Research Communications Messages

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Allergy and Infectious Diseases (NIAID), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: *Title:* Pretesting of NIAID's HIV Vaccine Research Communications Messages. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This is a request for clearance to pretest messages, materials and program activities produced for the NIAID HIV Vaccine Research Education Initiative (NHVREI). The primary objectives of the pretests are to (1) Assess audience knowledge, attitudes, behaviors and other characteristics for the planning/development of health messages, education products, communication strategies, and public information programs; and (2) pretest these health messages, products, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions. The information obtained from audience research and pretesting results in more effective messages, materials, and programmatic strategies. By maximizing the effectiveness of these messages and strategies for reaching targeted audiences, the frequency with which publications, products, and programs need to be modified is reduced. *Frequency of Response:* On occasion. *Affected Public:* Individuals. *Type of Respondents:* Adults at risk for HIV/AIDS, particularly those who are Black/African-American, Hispanic/Latino, or men who have sex with men; healthcare providers; representatives of organizations disseminating HIV-related messages or materials. The annual reporting burden is shown in the table below. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
At-risk Adults	3,374	1	.3422	1155
Healthcare providers	50	1	.75	37.5
Organization Gatekeepers	75	1	.50	37.5
Total	3,499			1230

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Katharine Kripke, Assistant Director, Vaccine Research Program, Division of AIDS, NIAID, NIH, 6700B Rockledge Dr., Bethesda, MD 20892–7628, or call non-toll-free number 301–402–0846, or e-mail your request, including your address to *kripkek@niaid.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: August 21, 2007.

John J. McGowan,

Deputy Director for Science Management, NIAID, National Institutes of Health.

[FR Doc. E7–17012 Filed 8–27–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Scientific Management Review Board (SMRB).

The NIH Reform Act of 2006 (Pub. L. 109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

Duration of this committee is tow years from the date of Charter is filed.

Dated: August 20, 2007.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. 07–4221 Filed 8–27–07; 8:45 am]

BILLING CODE 4140–01–M

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.

Development of Antigenic Chimeric St. Louis Encephalitis Virus/Dengue Virus Type Four Recombinant Viruses (SLEV/DEN4) as Vaccine Candidates for the Prevention of Disease Caused by SLEV

Description of Invention: St. Louis Encephalitis Virus (SLEV) is a mosquito-borne flavivirus that is endemic in the Americas and causes sporadic outbreaks of disease in humans. SLEV is a member of the Japanese encephalitis virus serocomplex and is closely related to West Nile Virus (WNV). St. Louis encephalitis is found throughout North, Central, and South America, and the Caribbean, but is a major public health problem mainly in the United States. Prior to the outbreak of West Nile virus in 1999, St. Louis encephalitis was the most common human disease caused by mosquitoes in the United States. Since 1964, there have been about 4,440 confirmed cases of St. Louis encephalitis, with an average of 130 cases per year. Up to 3,000 cases have been reported during epidemics in some years. Many more infections occur without symptoms and go undiagnosed. At present, a vaccine or FDA approved antiviral therapy is not available.

The inventors have previously developed a WNV/Dengue4Delta30 antigenic chimeric virus as a live attenuated virus vaccine candidate that contains the WNV premembrane and envelope (prM and E) proteins on a dengue virus type 4 (DEN4) genetic background with a thirty nucleotide deletion (Delta30) in the DEN4 3'-UTR. Using a similar strategy, the inventors have generated an antigenic chimeric virus, SLE/DEN4Delta30. Preclinical testing results indicate that chimerization of SLE with DEN4Delta30 decreased neuroinvasiveness in mice, did not affect neurovirulence in mice, and appeared to overattenuate the virus for non-human primates. Modifications of the SLE/DEN4Delta30 vaccine candidate are underway to improve its immunogenicity.

This application claims live attenuated chimeric SLE/DEN4Delta30 vaccine compositions and bivalent WNV/SLE/DEN4Delta30 vaccine compositions. Also claimed are methods of treating or preventing SLEV infection in a mammalian host, methods of producing a subunit vaccine composition, isolated polynucleotides comprising a nucleotide sequence encoding a SLEV immunogen, methods for detecting SLEV infection in a biological sample and infectious chimeric SLEV.

Application: Immunization against SLEV or SLEV and WNV.

Development Status: Live attenuated vaccine candidates are currently being developed and preclinical studies in mice and monkeys are in progress. Suitable vaccine candidates will then be evaluated in clinical studies.

Inventors: Stephen S. Whitehead, Joseph Blaney, Alexander Pletnev, Brian R. Murphy (NIAID).

Patent Status: U.S. Provisional Application No. 60/934,730 filed 14 Jun 2007 (HHS Reference No. E–240–2007/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize live attenuated virus vaccine candidates for St. Louis encephalitis virus. Please contact Dr. Whitehead at 301–496–7692 for more information.

Monoclonal Antibodies Against Dengue and Other Viruses With Deletion in Fc Region

Description of Invention: The four dengue virus (DENV) serotypes (DENV–1 to DENV–4) are the most important arthropod-borne flaviviruses in terms of morbidity and geographic distribution. Up to 100 million DENV infections occur every year, mostly in tropical and subtropical areas where vector mosquitoes are abundant. Infection with any of the DENV serotypes may be asymptomatic or may lead to classic dengue fever or more severe dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS), which are increasingly common in the dengue endemic areas. Immunity to the same virus serotype (homotypic immunity) is life-long, whereas immunity to different serotypes (heterotypic immunity) lasts