selected through a competitive peer review process, and managed as CDC cooperative agreements. Awards are made for five years and may be renewed through a continuation application. This program is authorized under sections 301(a) and 317b(k)(2) of the Public Health Service (PHS) Act, [42 U.S.C. sections 241(a) and 247b(k)(2)], as amended.

All funded programs are required to submit continuation applications and semi-annual progress reports consistent with federal requirements that all agencies, in response to the Government Performance and Results Act of 1993, prepare performance plans and collect program-specific performance measures.

An Internet-based management information system (MIS) will allow CDC to monitor, and report on state Heart Disease and Stroke Prevention Programs more efficiently. Data reported to CDC through the MIS will be used by CDC to identify training and technical assistance needs, monitor compliance with cooperative agreement requirements, evaluate progress made in achieving program-specific goals, and obtain information needed to respond to Congressional and other inquiries regarding program activities and effectiveness. There are no costs to respondents.

ANNUALIZED BURDEN TABLE:

Respondents	Number of respondents	Number of responses per respondent	Average burden per respondent (in hours)	Total burden hours
States and Washington, DC	33	2	6	396
Totals	33			396

Dated: June 29, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–15385 Filed 7–6–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 04100]

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Prevention Epicenter Program—Microbiology Errors Associated With Processing Blood and Sterile Body Site Cultures—The Impact of New Forms of Antimicrobial Use, Resistance, Laboratory Methods, and Infection Control Practices on the Incidence of Clostridium Difficile and Associated Patient Morbidity and Healthcare Costs

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting: Prevention Epicenter Program—Microbiology Errors Associated with Processing Blood and Sterile Body Site Cultures—The Impact of New Forms of Antimicrobial Use, Resistance, Laboratory Methods, and Infection Control Practices on the Incidence of Clostridium difficile and Associated Patient Morbidity and Healthcare Costs, Program Announcement Number 04100.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP).

Times and Dates: 8 a.m.–8:30 a.m., July 27, 2004 (Open). 8:45 a.m.–3:30 p.m., July 27, 2004 (Closed).

Place: Marriott Airport Hotel, 4711 Best Road, College Park, GA 30337, Telephone number 404–766–7900.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04100.

For Further Information Contact: Trudy Messmer, Ph.D., Scientific Review Administrator, National Center for Infectious Diseases, CDC, 1600 Clifton Road, NE., MS–C19, Atlanta, GA 30333, Telephone 404–639–2176.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 29, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–15386 Filed 7–6–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 04094]

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Applied Research on Antimicrobial Resistance (AR): Estimates of Economic Cost for Antimicrobial Resistant Human Pathogens of Public Health Importance

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Applied Research on Antimicrobial Resistance (AR): Estimates of Economic cost for Antimicrobial Resistant Human Pathogens of Public Health Importance, Program Announcement Number 04094.

Times and Dates: 8:30 a.m.–9 a.m., July 28, 2004 (Open). 9:15 a.m.–5:30 p.m., July 28, 2004 (Closed)

Place: Marriott Airport Hotel, 4711 Best Road, College Park, GA 30337, Telephone Number 404–766–7900.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Applied Research on Antimicrobial Resistance (AR): Estimates of Economic cost for Antimicrobial Resistant Human Pathogens of Public Health

Importance, Program Announcement Number 04094.

For Further Information Contact:

Trudy Messmer, Ph.D., Scientific Review Administrator, Centers for Disease Control, National Center for Infectious Diseases, 1600 Clifton Road NE., Mailstop C19, Atlanta, GA 30333, Telephone 404–639–2176.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 29, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04–15387 Filed 7–6–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003E–0405 and 2003E–0452]

Determination of Regulatory Review Period for Purposes of Patent Extension; NEUTERSOL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NEUTERSOL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of two applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of two patents which claim that animal drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product NEUTERSOL (zinc gluconate). NEUTERSOL is indicated for chemical sterilization in 3- to 10-month-old male puppies. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for NEUTERSOL (U.S. Patent Nos. 5,070,808 and 4,937,234) from Technology Transfer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of NEUTERSOL represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NEUTERSOL is 4,222 days. Of this time, 4,188 days occurred during the testing phase of the regulatory review period, and 34 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) involving this animal drug product became effective*: August 27, 1991. The applicant claims November 14, 1991, as the date the investigational new animal drug application (INAD) became effective. The applicant relied on this date based on a letter sent to the applicant by the document room on November 14, 1991 which provided the INAD number to the applicant. However, this letter was not intended to serve as an official acknowledgment of the INAD filing. FDA records indicate that the filing of a notice of claimed investigational exemption was August 27, 1991, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act*: February 12, 2003. The applicant claims February 10, 2003, as the date the new animal drug application (NADA) for NEUTERSOL (NADA 141–217) was initially submitted. However, FDA records reveal that NADA 141–217 was submitted on February 12, 2003.

3. *The date the application was approved*: March 17, 2003. FDA has verified the applicant's claim that NADA 141–217 was approved on March 17, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 7, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 3, 2005. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets