product label even absent those requirements.

William Blumenthal,

General Counsel.

[FR Doc. E5–7531 Filed 12–19–05; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Occupational Health and Safety Research, Program Announcement 04038 and Small Grants in Occupational Safety and Health, Program Announcement 04021

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): Occupational Health and Safety Research, Program Announcement 04038 and Small Grants in Occupational Safety and Health, Program Announcement 04021.

Time and Date: 1 p.m.–3 p.m., January 13, 2006 (Closed).

Place: National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE., Mailstop E–74, Atlanta, GA 30333 Telephone Number (404) 498–2582.

Status: 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 Public Law 92–463.

Matters To Be Considered: The meeting will include the review, discussion, and evaluation of applications received in response to: Occupational Health and Safety Research, Program Announcement 04038 and Small Grants in Occupational Safety and Health, Program Announcement 04021.

Contact Person For More Information: Charles Rafferty, Ph.D., Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE., Mailstop E–74, Atlanta, GA 30333, Telephone Number (404) 498–2582. 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: December 13, 2005.

Alvin Hall,

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

[FR Doc. E5–7550 Filed 12–19–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of Supplemental New Animal Drug Application; Tilmicosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The approved NADA provides for the veterinary prescription use of an injectable solution of tilmicosin phosphate for respiratory disease in cattle and sheep. This supplemental NADA adds user safety information to product labeling.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 140–929 for MICOTIL 300 (tilmicosin phosphate), an injectable solution available by veterinary prescription for use in the treatment and control of respiratory disease in cattle and in the treatment of respiratory disease in sheep. This supplemental NADA adds user safety information to product labeling related to the mechanism of toxicity and medical intervention. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)) and part 514 (21 CFR part 514) in §§ 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of December 2, 2005. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and § 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 8, 2005.

Bernadette Dunham,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 05–24269 Filed 12–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0485]

Regulatory Process for Pediatric Mechanical Circulatory Support Devices (Ventricular Assist Devices)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Regulatory Process for Pediatric Mechanical Circulatory Support Devices (Ventricular Assist Devices). The topics of discussion are the agency's activities regarding the regulation and approval of circulatory support devices used for temporary support in pediatric patients.

Date and Time: The public meeting will be held on January 20, 2006, from 9 a.m. to 12 p.m. The agency is requiring registration by December 30, 2005.

Location: The public meeting will be held at the Center for Devices and Radiological Health, rm. 20B, 9200 Corporate Blvd., Rockville, MD 20850.

Contact: Eric Chen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., 301–443–8262, ext. 146, e-mail: *eac@cdrh.fda.gov*, or Michael Berman (HFZ–170), 12725 Twinbrook Pkwy., 301–827–4744, e-mail: *mrb@cdrh.fda.gov*. If you need special accommodations due to a disability, please contact Eric Chen, at least 7 days in advance of the meeting.

Registration: There is no fee to attend the workshop; however, because space is limited, registration is required. Please submit registration information (including name, title, firm name, address, e-mail address, telephone number, and fax number) by December 30, 2005 (see *Contact*). Background information for the workshop will be