

product label even absent those requirements.

William Blumenthal,

General Counsel.

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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]

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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]

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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

available to the public on the Internet at <http://www.fda.gov/cdrh/meetings/012006workshop/index.html>.

SUPPLEMENTARY INFORMATION: This workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by providing the medical device community with guidance on the approval process for mechanical circulatory support devices (ventricular assist devices) used in pediatric patients in need of temporary support (left side, right side, or both sides). During the public workshop, FDA will present information regarding the approval process for these devices. Specifically, FDA will address applications for premarket approval, humanitarian use designations, humanitarian device exemptions, and investigational device exemptions. FDA will also present information regarding preclinical engineering qualification of pediatric mechanical circulatory support devices and invited experts will discuss medical and surgical topics. Following each presentation, and at the close of the meeting, FDA will conduct a question and answer session with the participating audience. After the workshop, presentations can be accessed by the public on the Internet at <http://www.fda.gov/cdrh/meetings/012006workshop/index.html>.

This workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which include working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed to small businesses.

Dated: December 12, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05-24271 Filed 12-19-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Notification of Intent To Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930-0234)—Revision

The Drug Addiction Treatment Act of 2000 ("DATA," Pub. L. 106-310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers.

To implement these new provisions, SAMHSA developed a notification form (SMA-167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (*i.e.*, independent physicians and physicians in group practices (as defined under section 1877(h)(4) of the Social Security Act) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will

assign an identification number to qualifying practitioners; this number will be included in the practitioner's registration under 21 U.S.C. 823(f).

Practitioners may use the form for two types of notification: (a) New, and (b) immediate. Under "new" notifications, practitioners may make their initial waiver requests to SAMHSA.

"Immediate" notifications inform SAMHSA and the Attorney General of a practitioner's intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii).

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location, telephone and fax numbers; e-mail address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification new, immediate, or renewal; certification of qualifying criteria for treatment and management of opiate dependent patients; certification of capacity to refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to disclose limited information available on <http://www.buprenorphine.samhsa.gov>.

Since July 2002, SAMHSA has received approximately 6,400 notifications and has certified over 5,500 physicians. Eighty-one percent of the notifications were submitted by mail or by facsimile, with approximately twenty percent submitted through the Web based online system.

Approximately 60 percent of the certified physicians have consented to disclosure on <http://www.buprenorphine.samhsa.gov>.

Respondents may submit the form electronically, through a dedicated Web page that SAMHSA will establish for the purpose, as well as via U.S. mail.

The following table summarizes the estimated annual burden for the use of this form.

Purpose of submission	Number of respondents	Responses per respondent	Burden per response (hr.)	Total burden (hrs)
Initial Application for Waiver	2,000	1	.066	132
Notification to Prescribe Immediately	50	1	.083	3