

Analysis and Services Office, CDC pursuant to Public Law 92-463. Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Ms. Amy Harris, Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE., M/S F-63, Atlanta, Georgia 30341-3724, telephone (770) 488-4936.

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 3, 2008.

**Elaine L. Baker,**

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

[FR Doc. E8-12892 Filed 6-6-08; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health, (NIOSH)

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 of the aforementioned committee:

#### *Times and Dates:*

8 a.m.-5 p.m., June 26, 2008 (Closed);

8 a.m.-5 p.m., June 27, 2008 (Closed).

*Place:* Embassy Suites Hotel, 1900

Diagonal Road, Alexandria, Virginia 22314, Telephone (703) 684-5900, Fax (703) 684-1403.

*Purpose:* The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

These 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, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92-463.

*Matters To Be Discussed:* The meeting will convene to address matters related to the conduct of Study Section business and to consider Safety and Occupational Health-Related Grant Applications.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Price Connor, PhD, NIOSH Health Scientist, 1600 Clifton Road, NE., Mailstop E-20, Atlanta, Georgia 30333, Telephone (404) 498-2511, Fax (404) 498-2571.

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: May 30, 2008.

**Elaine L. Baker,**

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

[FR Doc. E8-12793 Filed 6-6-08; 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; Moxidectin

**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 Fort Dodge Animal Health, Division of Wyeth. The approved NADA provides for the veterinary prescription use of a sustained-release injectable moxidectin formulation for prevention of heartworm disease and treatment of existing hookworm infections in dogs. The supplemental NADA adds animal safety information to product labeling.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141-189 that provides for veterinary prescription use of PROHEART 6 (moxidectin) Sustained Release

Injectable for Dogs, used for prevention of heartworm disease and treatment of existing hookworm infections. The supplemental NADA updates the warning, precaution, adverse reactions, and post-approval experience sections of product labeling. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of May 23, 2008.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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.

The agency has determined under 21 CFR 25.33(d)(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: June 2, 2008.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 08-1329 Filed 6-5-08; 12:00 pm]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Cardiovascular and Renal Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on June 25, 2008, from 8 a.m. to 5 p.m.

*Location:* Hilton Washington DC/ Silver Spring, Maryland Ballroom, 8727

Colesville Rd., Silver Spring, MD, 301-589-5200.

Contact Person: Elaine Ferguson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [elaine.ferguson@fda.hhs.gov](mailto:elaine.ferguson@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss new drug application (NDA) 22-275, tolvaptan (proposed trade name SAMSKA), Otsuka Pharmaceutical Development & Commercialization, Inc., for the proposed indication of treatment of hypervolemic and euvoemic, hyponatremia. The committee will hear presentations from FDA and the sponsors specifically regarding change in sodium level as basis for drug approval.

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.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 20, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

requested to make their presentation on or before June 13, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 16, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

FDA regrets that it was unable to publish this notice 15 days prior to the June 25, 2008, Cardiovascular and Renal Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Cardiovascular and Renal Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 2, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E8-12868 Filed 6-6-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on July 15, 2008, from 8 a.m. to 5 p.m.

**Location:** Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

**Contact Person:** Ronald P. Jean, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3676, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss, make recommendations, and vote on a premarket approval application for Oxiplex/SP Gel, sponsored by FzioMed, Inc. This device is intended to be used as a surgical adjuvant during posterior lumbar laminectomy, laminotomy, or discectomy to improve patient outcomes by reducing postoperative leg pain, back pain, and neurological symptoms.

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.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending