

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine—21 CFR Part 10.75 (OMB Control Number 0910-0566)—Extension**

CVM's "Guidance for Industry #79—Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary

Medicine" describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the agency intends to interpret and apply provisions of the existing regulations regarding internal agency review of decisions. In addition, the guidance outlines the established recommended procedures for persons who are applicants, including sponsor

applicants or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When an applicant has a scientific disagreement and a written decision by CVM, the applicant may submit a request for review of that decision by following the established agency channels of supervision for review.

Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.75	2	4	8	10	80

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents multiplied by the annual frequency of response equals the total annual responses. The number of hours per response is based on discussions with industry and may vary depending on the complexity of the issue(s) involved and the duration of the appeal process.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 18, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-6065 Filed 3-25-08; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Anesthetic and Life Support 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:* Anesthetic and Life Support 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 May 7, 2008, from 8 a.m. to 4:30 p.m.

*Location:* Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD, 301-948-8900.

*Contact Person:* Teresa Watkins, 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: [Teresa.Watkins@fda.hhs.gov](mailto:Teresa.Watkins@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in Washington, DC area), code 3014512529. 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:* On May 7, 2008, the committee will discuss new drug

application (NDA) 22-244, fospropofol disodium injection (35 milligrams/milliliter) (proposed tradename Aquavan), MGI Pharma, Inc., for the proposed indication of sedation in adult patients undergoing diagnostic or therapeutic procedures.

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 April 23, 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 April 15, 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 April 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 Teresa Watkins 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.

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

Dated: March 20, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E8-6193 Filed 3-25-08; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Blood Products 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). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Blood Products 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 May 1, 2008, from 8:30 a.m. to 5:30 p.m. and on May 2, 2008, from 8:30 a.m. to 4 p.m.

*Location:* Hilton Hotel, Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Donald W. Jehn or Pearlina K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. 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:* On the morning of May 1, 2008, the committee will hear updates on the following: (1) Summaries of August 22-23, 2007, and January 9-10, 2008, meetings of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability; (2) 2007 West Nile Virus Epidemiology and the use of nucleic acid tests to reduce the risk of transmission of West Nile Virus in Whole Blood and blood components for transfusion and Human Cells, Tissues, and Cellular and Tissue-based products (HCT/PS); (3) implementation of blood donor screening for infection with *Trypanosoma cruzi* and the use of serological tests to reduce the risk of transmission of *T. cruzi* infection in Whole Blood and blood components for transfusion and HCT/PS; (4) FDA's proposal to lower the minimum recommended lot release titer for measles antibodies in Immune Globulin Intravenous (Human) and Immune Globulin Subcutaneous (Human); (5) Gambro/Fenwal Post Approval Surveillance Study of Platelet Outcomes, Release Tested (PASSPORT) Post Marketing Study—7 Day Platelets; (6) Experience with 7 Day Platelets Versus 5 Day Platelets; and (7) FDA Perspective on the PASSPORT Study. These updates will be followed by informational presentations on FDA's Center for Biologics Evaluation and Research Safety Teams related to blood and tissue. In the afternoon, the committee will discuss the Biomedical Excellence for Safer Transfusion Committee Report on red blood cell recovery standards. On the morning of May 2, 2008, the committee will discuss Lev Pharmaceutical's plasma-derived C1 esterase inhibitor (CINRYZE). Then, in the afternoon the committee will review

the research programs in the Laboratory of Hepatitis and Related Emerging Agents, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, CBER Site Visit of November 8, 2007.

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:* The entire day of May 1, 2008, and on May 2, 2008, from 8:30 a.m. to 3:15 p.m., the meeting is open to the public. 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 April 23, 2008. Oral presentations from the public will be scheduled between approximately 11:50 a.m. and 12:20 p.m. and between approximately 4:20 p.m. and 4:50 p.m. on May 1, 2008, and between approximately 10:40 a.m. and 11:10 a.m. and 2:40 p.m. and 3 p.m. on May 2, 2008. 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 April 15, 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 April 16, 2008.

*Closed Committee Deliberations:* On May 2, 2008, between 3:15 p.m. and 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the