

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 only through FDMS at <http://www.regulations.gov>.

Dated: July 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-15766 Filed 7-10-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Approaches to Reduce Risk of Transfusion-Transmitted Babesiosis in the United States; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Approaches to Reduce the Risk of Transfusion-Transmitted Babesiosis in the United States." The purpose of the public workshop is to discuss the risk and possible approaches to minimize the incidence of transfusion-transmitted babesiosis in the United States. We are convening this workshop at the present time because FDA has observed a recent increase in the number of reports of transfusion-transmitted babesiosis, thus warranting additional discussion to address this blood safety issue. The public workshop will feature presentations and roundtable discussions led by experts from academic institutions, government, and industry.

Date and Time: The public workshop will be held on September 12, 2008, from 7:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Lister Hill Center Auditorium, Bldg. 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: rhonda.dawson@fda.hhs.gov.

Registration: Mail, fax or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 25, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited to 175 attendees. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Babesiosis is a malaria-like illness caused by infection of erythrocytes with protozoan parasites belonging to the genus *Babesia*. Transfusion-transmitted babesiosis is caused by transfusion of blood or blood components collected from donors infected with *Babesia* parasites. During the last 40 years, more than 60 cases of transfusion-transmitted babesiosis have been recognized in the United States. In fiscal years 2006 and 2007, FDA received a total of five reports of fatal transfusion-transmitted babesiosis (primary or contributory cause of death) in the United States.

The public workshop will facilitate a scientific discussion on approaches to reduce the risk of transfusion-transmitted babesiosis in the United States. Topics to be discussed include: (1) Biology, pathogenesis, transmission and epidemiology of babesiosis; (2) risk of *Babesia* infections through transfusion of blood and blood components; (3) laboratory testing to detect *Babesia* infections; and, (4) possible approaches, including donor testing and donor deferral, to reduce the risk of transfusion-transmitted babesiosis while maintaining blood availability and safety.

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Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: July 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-15799 Filed 7-10-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Committee, Food Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Food Advisory Committee (FAC), Center for Food Safety and Applied Nutrition (CFSAN).

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations received on or before August 11, 2008 will be given first consideration for membership on the Food Advisory Committee. Nominations received after August 11, 2008 will be considered for nomination to the committee should nominees still be needed.

ADDRESSES: All Nominations for membership should be sent electronically to CV@FDA.HHS.GOV or by mail to: Advisory Committee Oversight and Management Staff, 5600 Fisher Lane (HF-4), rm. 15A-12, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is Carolyn Jeletic, Center for Food Safety and Applied Nutrition, 301-436-1913, FAX: 301-436-2633, e-mail: