

a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0497. The approval expires on May 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 20, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 02-29927 Filed 11-25-02; 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). The meeting will be open 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 December 12, 2002, from 8 a.m. to 6 p.m.

*Location:* Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact:* Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On December 12, 2002, the following committee updates are tentatively scheduled: (1) Summary of West Nile Virus workshop, November 4 and 5, 2002; (2) Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), and (3) human immunodeficiency virus (HIV) rapid tests. In the morning, the committee will hear presentations, and discuss and provide recommendations on the topic of bacterial contamination. In the

afternoon, the committee will hear presentations on human parvovirus B19 nucleic acid testing for whole blood and source plasma, and discuss and provide recommendations.

*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 by November 22, 2002. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 12:15 p.m. and 4:30 p.m. and 5 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 22, 2002, 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.

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 Linda A. Smallwood or Pearlina K. Muckelvene at 301-827-1281 at least 7 days in advance of the meeting.

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

Dated: November 20, 2002.

**Linda Arey Skladany,**

*Associate Commissioner for External Relations.*

[FR Doc. 02-29928 Filed 11-25-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 94D-0147]

#### Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#80) entitled "Guidance for

Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds." The guidance explains the standards upon which studies to establish the utility of anti-Salmonella chemical food additives for maintaining feeds Salmonella-negative should be based. The intended effect of this guidance is to provide advice on study standards for the establishment of anti-Salmonella food additives that will maintain feeds Salmonella-negative.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the final guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the final guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Henry E. Ekperigin, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0174, e-mail: [hekperig@cvm.fda.gov](mailto:hekperig@cvm.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In April 1991, FDA publicly discussed its intention to adopt a policy requiring feeds and feed ingredients to be *Salmonella*-free (meeting of FDA's Veterinary Medicine Advisory Committee, April 11, 1991, Bethesda, MD). The agency later adopted a policy requiring feeds and feed ingredients to be *Salmonella*-negative (see 59 FR 33975, July 1, 1994). This reflected concerns that *Salmonella* infections cause a significant portion of foodborne illnesses, and that animal feeds are a significant source of *Salmonella* infections in food animals and thus in humans. After the issuance of the *Salmonella*-negative policy, development began on several products designed to achieve and maintain *Salmonella*-negative levels in animal feeds. Sponsors of these products may file food additive petitions to establish the safety and utility of the additives. Because sponsors have used a variety of research methods to support their petitions, FDA has found it difficult to

evaluate the petitions in a uniform manner.

In an effort to achieve more consistency, FDA developed a draft guidance entitled "Utility Studies for Anti-Salmonella Chemical Food Additives in Animal Feeds." The availability of this draft guidance was announced in the **Federal Register** of June 23, 1994 (59 FR 32442). A public workshop on this topic was held on August 8, 1994, in conjunction with the annual meeting of the Poultry Science Association in Starkville, MS. Comments at the public workshop and the written comments received on the draft guidance led FDA to revise the draft document. The agency clarified several statements that had caused confusion or had raised questions among the respondents. Further, following suggestions from the respondents, the agency made several changes in the testing methods.

The purpose of this final guidance is to support consistent evaluation of anti-Salmonella food additives and their ability to maintain a Salmonella-negative level in previously "clean" animal feeds through repeated exposure to various Salmonella serotypes. This guidance should help ensure that sponsors conduct appropriate studies to evaluate the utility of anti-Salmonella food additives, and that FDA accomplish uniform review and decisionmaking. In turn, this should facilitate the approval process for such food additives.

This final guidance explains the recommended experimental process in detail and references other FDA documents that pertain to general experimental practices and procedures recommended by FDA. The guidance provides details concerning recommended testing methods.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The final guidance represents the agency's current thinking on anti-Salmonella food additives for keeping feeds Salmonella-negative. It does not create or confer any rights for or on any

person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**

There are nine or fewer respondents to the information collection described in this guidance and therefore no burden analysis is required under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

*Title:* Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds.

*Description:* In 1990, FDA announced its goal of Salmonella-negative animal feed and feed ingredients (see 59 FR 33975, July 1, 1994). The policy responds to concerns that Salmonella infections cause a significant portion of foodborne illnesses, and that animal feeds serve as a significant source of Salmonella infections in food animals and consequently in humans. In response, sponsors have developed several products designed to achieve and maintain Salmonella-negative levels in animals feeds. The sponsors also have filed the requisite food additive petitions that prove both the safety and utility of the additive products. However, up to this point, it has been difficult for FDA to evaluate the petitions in a consistent manner, as the research methods supporting the petitions have varied to a significant degree.

This final guidance document describes standards upon which studies to establish the utility of anti-Salmonella chemical food additives for maintaining feeds Salmonella-negative should be based. Certain types of information should be collected in these studies, as described in the final guidance.

**IV. Comments**

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this final guidance at any time. Two copies of any comments are to be submitted, except

that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public inspection in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cvm>.

Dated: November 15, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Fiscal Year (FY) 2003 Funding Opportunities**

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of funding availability for Community Collaborations to Prevent Youth Violence and Promote Youth Development (short title: Youth Violence Prevention Grants).

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) announces the availability of FY 2003 funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants *must* obtain a copy of the Request for Applications (RFA), including part I, Community Collaborations to Prevent Youth Violence and Promote Youth Development (SM 03-005) (short title: Youth Violence Prevention Grants), and part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Est. funds FY 2003	Est. number of awards	Project period (years)
Community Collaborations to Prevent Youth Violence and Promote Youth Development.	Jan. 22, 2002 .....	\$4,000,000	24	2

The actual amount available for the award may vary depending on unanticipated program requirements and actual SAMHSA appropriations.

This program is being announced prior to the annual appropriation for FY 2003 for SAMHSA's programs. Applications are invited based on the assumption that

sufficient funds will be appropriated for FY 2003 to permit funding of Community Collaborations to Prevent Youth Violence and Promote Youth