

approximately 2:30 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 10, 2004, 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 Beverly O'Neill at 301-827-7001, 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: February 12, 2004.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-3645 Filed 2-18-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Vaccines and Related Biological 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:* Vaccines and Related Biological 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 March 17, 2004, from 1 p.m. to 5 p.m.

*Location:* Food and Drug Administration, 8800 Rockville Pike, Bldg. 29B, Conference Room C, Bethesda, MD. This meeting will be held by a telephone conference call. The

public is welcome to attend the meeting at the previously mentioned location. A speaker telephone will be provided at the specified location for public participation in this meeting.

*Contact Person:* William Freas or Denise H. Royster, Food and Drug Administration, Center for Biologics Evaluations and Research (HFM-71), 1401 Rockville Pike, 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 3014512391. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* This committee will discuss recommendations pertaining to the influenza virus vaccine formulation.

*Procedure:* On March 17, 2004, from 1 p.m. to 5 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 by March 11, 2004. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 11, 2004, 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.

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

Dated: February 11, 2004.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1993D-0398]

#### Guidance for Industry: Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#52) entitled "Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora." This guidance is a revision of the guidance document #52 entitled "Microbiological Testing of Antimicrobial Drug Residues in Food," which was implemented in 1996. In this guidance, the agency recommends a pathway approach for assessing the microbiological safety of antimicrobial drug residues in food, rather than the approach described in the 1996 version of the guidance. The agency's decision to revise this guidance is based on new information available to the agency.

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

**ADDRESSES:** Submit written comments on this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

#### FOR FURTHER INFORMATION CONTACT:

Haydee Fernandez, Center for Veterinary Medicine (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6981, e-mail: [afernand@cvm.fda.gov](mailto:afernand@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**