

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1146]

Discussion of “Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern;” Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: “Discussion of Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern.” The topic to be discussed is this draft guidance document that describes an approach for implementing concepts previously considered in the FDA framework document on antimicrobial resistance (64 FR 887, January 6, 1999). The draft guidance outlines a method for assessing the safety of antimicrobial new animal drugs intended for use in food-producing animals.

Date and Time: The public meeting will be held on Wednesday, October 2, 2002, from 9 a.m. to 5 p.m. Interested persons, who wish their comments to be considered during the meeting, may submit written or electronic comments by September 25, 2002, to the Dockets Management Branch (see *Comments and Electronic Access*).

Location: The meeting will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, 20852, 301-468-1100.

Comments and Electronic Access. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of written comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title and Docket No. 98D-1146 found in brackets in the heading of this document. A copy of the received comments is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Oral comments regarding the draft guidance may be provided during the public comment sessions. Since time for public comments is limited, prior notification of your intent to comment is encouraged. Please register and submit a short summary of your comments by September 25, 2002; faxed copies of comments are permissible. We encourage consolidation of like-minded presentations to provide sufficient opportunity for public comment.

For General Information Contact: Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4515; FAX 301-827-4335 or e-mail: asindela@cvm.fda.gov.

For Information About Registration/Oral Comments Contact: Anna Roy, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-2947; FAX 301-827-4335 or e-mail: aroy@cvm.fda.gov.

Registration: Registration is required. There is no registration fee for the meeting. Limited space is available, and early registration is encouraged.

Registration forms are available on the Dockets Management Branch Web site at www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm

If you need special accommodations for a disability, please contact the DoubleTree Hotel at least 7 days in advance of the meeting.

Meeting Agenda: The meeting will consist of a series of oral presentations in the morning to explain the content of the draft guidance document. The agenda in the afternoon will consist primarily of sessions to address specific questions and to provide opportunity for public comment. The meeting agenda will be made available on the CVM Web site at www.fda.gov/cvm/antimicrobial/ar_meetings.htm.

Transcripts: You may request a transcript of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857. The transcript of the public meeting will be after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Dockets Management Branch (see *Comments and Electronic Access*) between 9 a.m. and 4 p.m., Monday through Friday and on the CVM Web site at www.fda.gov/cvm/antimicrobial/ar_meetings.htm.

SUPPLEMENTARY INFORMATION:

Background

In January 1999, FDA announced the availability of a discussion document entitled “Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals” (framework document) (64 FR 887, January 6, 1999). The framework document laid out possible strategies for managing the

potential risks associated with use of antimicrobial drugs in food-producing animals.

The current draft guidance document outlines an approach for implementing concepts described in the Framework Document. The draft document provides guidance on a risk analysis process as a possible means for evaluating antimicrobial resistance concerns as part of the preapproval safety evaluation of a new animal drug. The new animal drug sponsor may use this guidance and the methodology described to conduct a qualitative risk assessment to help evaluate antimicrobial resistance concerns as part of an overall preapproval safety evaluation of their proposed animal drug product. If the sponsor elects to use this process, the qualitative antimicrobial resistance risk assessment and supporting data should be submitted to FDA for review. FDA's purpose in this guidance is to ensure that antimicrobial new animal drugs intended for use in food-producing animals are safe with regard to human health.

Also in this issue of the **Federal Register**, FDA is publishing the notice of availability of the guidance document entitled "Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern."

Dated: September 9, 2002.

Margaret M. Dotzel

Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S