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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0969]

**Establishment of Resistance and Monitoring Thresholds in Food-Producing Animals;
Public Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Public Meeting Regarding the Establishment of Resistance and Monitoring Thresholds in Food-Producing Animals. The topic to be discussed is the Center for Veterinary Medicine's (CVM's) current thinking on concepts for the establishment of resistance and monitoring thresholds in food-producing animals. CVM will seek scientific input from experts at this meeting on these concepts as well as suggestions for alternative approaches.

Date and Time: The meeting will be held on October 10 and 11, 2000, 8:30 a.m. to 5 p.m.

Written comments may be submitted until December 11, 2000.

Addresses: The meeting will be held at The DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

For general inquiries about the meeting and registration contact: Lynda W. Cowatch, Center for Veterinary Medicine (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5281, FAX: 301-594-2298.

For technical inquiries contact: Aleta Sindelar, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0148.

Registration: Registration is required. There is no registration fee for the meeting. Limited space is available, and early registration is encouraged. Logistics for the meeting and the registration form are available on the Internet at <http://www.fda.gov/cvm/fda/mappgs/registration.html>. Please send the registration form to Lynda Cowatch (address above). Additional information about the meeting and the agenda will be available on the Internet (Internet site above) before the meeting.

If you need special accommodations due to a disability, please contact the DoubleTree Hotel at least 7 days in advance, 800-222-8733.

Transcripts: Transcripts of the meeting will be available on the Internet at <http://www.fda.gov/cvm>.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 1999 (64 FR 887), FDA announced the availability of a discussion paper entitled "A 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" (the Framework Document). FDA made the Framework Document available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health. This document discussed several risk management approaches to the regulatory management of antimicrobial drug resistance associated with food-producing animal use of antimicrobials. These strategies covered both preapproval and postapproval approaches and included: (1) Revision of the preapproval safety assessment for antimicrobial resistance for new animal drug applications to assess all uses for microbial safety, (2) categorization of antimicrobials based upon the importance of the drug for human medicine and upon which pre- and postapproval requirements would be based, (3) postapproval monitoring of the development of antimicrobial drug resistance and, (4) elaboration of resistance and monitoring thresholds.

The Framework Document discussed the concept of two thresholds, the resistance threshold and the monitoring threshold, that would be established prior to the approval of an antimicrobial new animal drug for use in food-producing animals to ensure that food products derived from treated animals are safe for consumers. The resistance threshold would be established in humans to represent the upper limit of resistant bacteria that can be transferred from animals to consumers. The Framework Document discussed the possibility of establishing resistance thresholds based on human data, animal data, or both.

Monitoring thresholds would also be established to guide the postapproval monitoring of resistance development in animals. According to the Framework Document, a monitoring threshold would need to be determined for each antimicrobial prior to approval, and the threshold may vary depending on the human or animal pathogen of concern. Monitoring thresholds would be established in animals so that they would serve as an early warning system, signaling when loss of susceptibility or resistance prevalence is approaching the resistance threshold.

If a monitoring threshold were reached, the drug sponsor would implement mitigation actions to address the loss of susceptibility or increasing resistance trend. If mitigation were not successful, and resistance continued to increase and reach the resistance threshold, withdrawal of the approval of the drug for the use(s) of concern would be warranted.

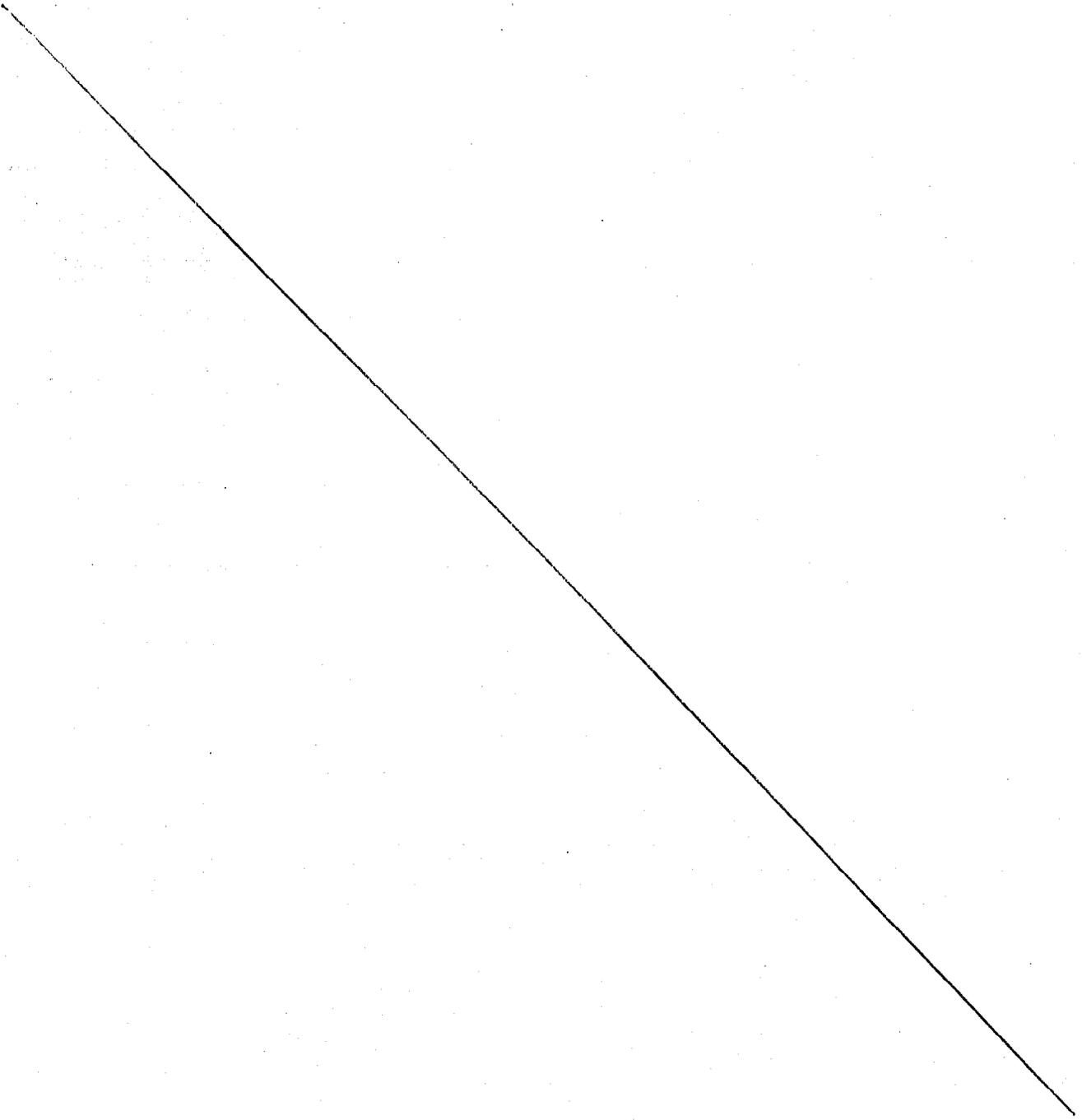
II. Submission of Comments

Interested persons may submit written comments regarding this meeting until December 11, 2000. Written comments should be submitted to the Dockets Management Branch (address above), or by fax to 301-827-6870. Comments should be identified with the docket number found in the brackets in the heading of this document.

III. Related Information

Transcripts of the three previous CVM public meetings on antimicrobial resistance, related public comments, the "Draft Risk Assessment on the Human Health Impact of Fluoroquinolone

Resistant Campylobacter Associated with the Consumption of Chicken (Revised as of February 9, 2000),” and “A 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” can be found on the Internet at <http://www.fda.gov/cv/llr/lda/mappgs/antitoc.html>.

Dated: 7/20/00
July 20, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

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