

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0969]

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Antimicrobial Resistance in Food-Producing Animals; Notice of General Public Meeting and Public Workshops; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) will sponsor a general public meeting and two public workshops to discuss important issues related to antimicrobial resistance (AR) in food-producing animals. The agency is seeking public comment on the general public meeting in its further planning of the two public workshops.

DATES: The general public meeting and the public workshops are scheduled as follows:

1. "General Public Meeting," Monday, October 4, 1999, 1 p.m. to 5 p.m.
2. "The Risk Assessment and the Establishment of Resistance Thresholds Workshop," Thursday and Friday, December 9 and 10, 1999, 9 a.m. to 5 p.m.
3. "Preapproval Studies in AR," Tuesday and Wednesday, February 22 and 23, 2000, 9 a.m. to 5 p.m.

ADDRESSES: The general public meeting and the public workshops will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, 301-468-1100.

FOR FURTHER INFORMATION CONTACT:

For general information regarding the general public meeting and public workshops: Lynda W. Cowatch, Center for Veterinary Medicine (CVM) (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5281, e-mail: lcowatch@cvm.fda.gov.

For information regarding technical inquiries: Sharon R. Thompson or Aleta M. Sindelar at 301-594-1798, FAX 301-594-1830.

Registration: The general public meeting and the public workshops are free, however, registration is required. Limited space is available and early registration is encouraged. Registration forms are available on CVM's home page at "<http://www.fda.gov/cvm/fda/mappqs/arregis1.doc>". If you need special accommodations for a disability, please contact the DoubleTree Hotel at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The agency believes it is essential to provide opportunities for public input regarding the following:

I. The General Public Meeting

The general public meeting is intended to provide an opportunity for stakeholders to give input to FDA on the appropriate issues, experts, and agenda items to be included in two subsequent scientific workshops related to AR. In general terms, the first scientific public workshop on December 9 and 10, 1999, is intended to focus on issues related to risk assessment and the establishment of resistance thresholds in food-producing animals. The second scientific public workshop on February 22 and 23, 2000, is intended to discuss the design of preapproval studies in food-producing animals to model the rate and extent of resistance development. FDA will consider comments received at the general public meeting in its further planning of the two scientific public workshops. We also encourage the submission of written comments at any time, but no later than 30 days after the date of publication of this notice to ensure time for full consideration in planning the December meeting. Comments should be identified with the docket number found in brackets in the heading of this document and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

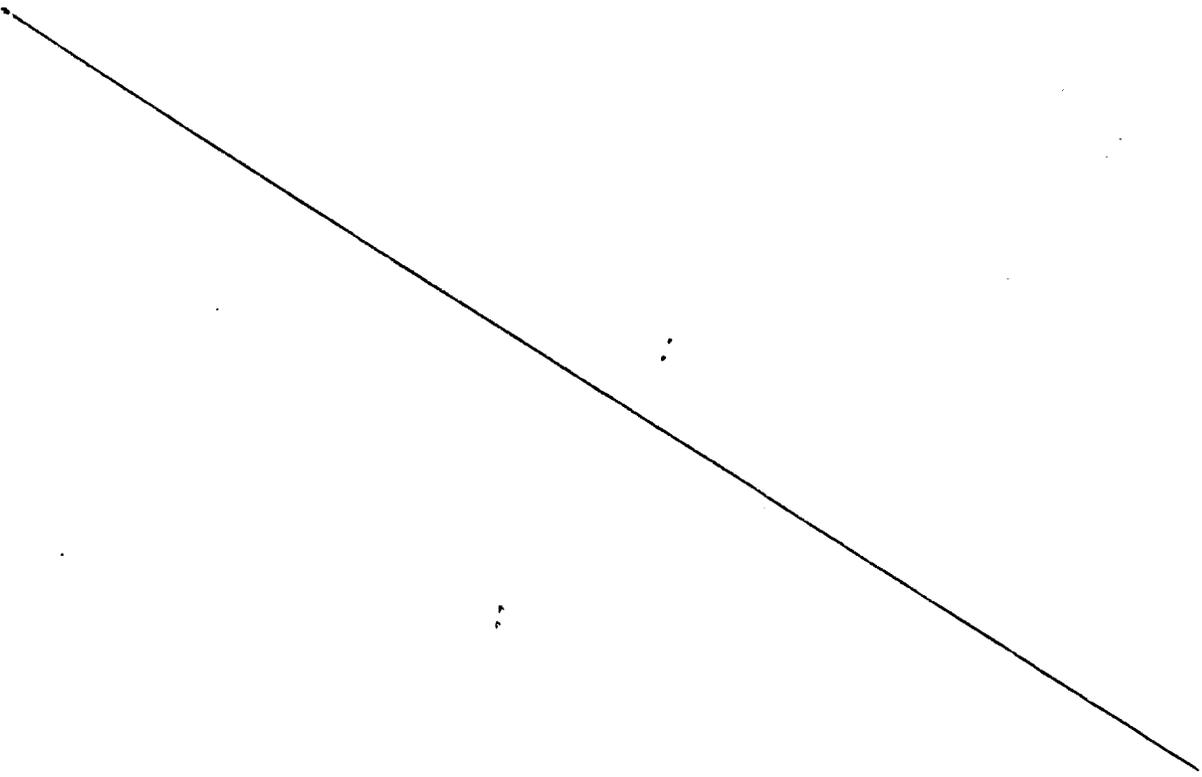
II. The Risk Assessment and the Establishment of Resistance Thresholds Workshop

The risk assessment and the establishment of resistance thresholds workshop is intended to allow a public discussion of FDA's risk assessment model to evaluate the risk to human health from resistant foodborne pathogens associated with the use of antimicrobials in food-producing animals. The meeting will also discuss FDA's current thinking on the use of this model to establish resistance and monitoring thresholds in food-producing animals. The agency seeks scientific input from experts at the meeting on these issues as well as suggestions for alternative approaches.

III. The Preapproval Studies in AR

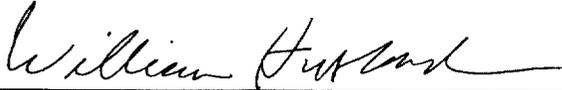
The preapproval studies in AR public workshop is intended to allow a public discussion of FDA's current thinking on the appropriate design of preapproval studies in food-producing animals to model the rate and extent of resistance development. The agency will seek suggestions for alternative approaches.

Supportive documents for discussion, including the "Framework Document," can be found on CVM's Internet home page at <http://www.fda.gov/cvm>. Information including meeting agendas



and relevant background information will be posted on the CVM home page in anticipation of each meeting and workshop.

Dated: September 22, 1999



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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