DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

Use of Antimicrobial Drugs in Food Animals and Establishment of Regulatory Thresholds on Antimicrobial Resistance; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is amending an announcement of the following meeting: Use of Antimicrobial Drugs in Food Animals and Establishment of Regulatory Thresholds on Antimicrobial Resistance. 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. This documents amends the date and title of the meeting (formally entitled ''Establishment of Resistance and Monitoring Thresholds in Food-Producing Animals'') that we previously announced in the **Federal Register** of July 28, 2000 (63 FR 46464), and amended on September 26, 2000 (65 FR 57820).

Date and Time: The meeting will be held on January 22 through 24, 2001, 8:30 a.m. to 5 p.m.

Location: The meeting will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD.

For Further Information Contact: 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 M. 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 W. Cowatch (address above). Additional information about the meeting and the agenda will be available on the Internet (address above) before the meeting.

If you need special accommodations due to a disability, please contact the DoubleTree Hotel at least 7 days in advance, 1–800–222–8733.

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

Dated: December 21, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–33371 Filed 12–28–00 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

RIN 00N–1686

Electronic Investigational New Drug Application: Cumulative Table of Contents; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the possibility of using extensible markup language (XML) to create a cumulative table of contents for investigational new drug applications (IND's) intended to be submitted electronically to the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER). Although the agency does not yet have a comprehensive approach to accepting IND's in electronic format in place of paper, it is updating existing guidance to make electronically submitted IND's in place of paper possible in the future. The agency is hoping to gain public input at the meeting on the use of XML to create a cumulative table of contents.

DATES: The public meeting will be held on January 26, 2001, from 8 a.m. to 4 p.m. Submit registration request by January 17, 2001. Written comments on the use of XML to create a cumulative table of contents are welcome at any time.

ADDRESSES: The public meeting will be held in the CDER Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, e-mail: levinr@cder.fda.gov, or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–025), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373, e-mail: yetter@cber.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is holding a public meeting to discuss the possibility of using XML to create a cumulative table of contents for IND's intended to be submitted electronically to CBER or CDER. The agency is updating guidance to make electronically submitted IND's in place of paper possible in the future. The agency is interested in input from the public on the following questions related to the use of XML to create a cumulative table of contents:

- Would a cumulative table of contents offer you advantages?
- How difficult is it for you to create and maintain the XML files needed for the cumulative table of contents?
- How difficult will it be for you to incorporate the preparation of an XML document in your submission preparation process?
- Do you have suggestions for improvements on the cumulative table of contents?
- Are you interested in piloting the cumulative table of contents in electronic IND's with the agency?
- Are you interested in working with us to develop tools to be used with the cumulative table of contents?
- Do you have other comments or suggestions?

An agenda and other materials including an example of a cumulative table of contents will be available prior to the meeting on the Internet at http://www.fda.gov/cder/regulatory/ersr/default.htm. Although there is no fee, preregistration by January 17, 2001, is required for all attendees at this meeting. Participation is limited to the first 100 registrants. To accommodate the greatest number of interested parties, registration is limited to persons outside FDA, and no more than two persons from an individual company should attend. Persons interested in attending the meeting should register by sending the names of those attending with the name of their company in an e-mail message to embreyj@cder.fda.gov.

The location of the meeting is 5630 Fishers Lane, next to the Parklawn Bldg. Please use the lower entrance, which faces Parklawn Dr. Visitor badges will be held at the guard station at the entrance to the building. Participants will need picture identifications to pick up their badge. Public parking is not available at the 5630 Fishers Lane location. A public parking lot is available on Fishers Lane across from the Parklawn Bldg., and additional public parking is available at the

Twinbrook Metro Station located several blocks west of the meeting location.

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments on the use of XML to create a cumulative table of contents. 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. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 22, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–33370 Filed 12–28–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1677]

Discussion Paper: An Approach for Establishing Thresholds in Association With the Use of Antimicrobial Drugs in Food-Producing Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a discussion paper entitled ''An Approach for Establishing Thresholds in Association With the Use of Antimicrobial Drugs in Food-Producing Animals (discussion paper).'' This discussion paper reflects the Center for Veterinary Medicine's (CVM's) current thinking on one concept for establishing resistance thresholds for antimicrobial drugs used in food-producing animals. The concept will be presented for discussion at a public meeting on January 22 to 24, 2001. CVM wants to receive comment on scientific and policy issues regarding this concept, as well as suggestions for alternative approaches.

DATES: Submit written comments on this discussion paper by April 9, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the discussion paper. Persons without Internet access may submit written requests for single copies of this discussion paper to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *For general inquiries:* Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail at sthompso@cvm.fda.gov.

For technical inquiries: William T. Flynn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570, e-mail at wflynn@cvm.fda.gov.

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 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 new policy for evaluating and ensuring that antimicrobial drug use in food-producing animals is safe for the public health. The Framework Document discussed several strategies for addressing concerns regarding the development of antimicrobial drug resistance associated with the use of antimicrobial drugs in food-producing animals. 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 consider all uses of antimicrobial drugs in food-producing animals, (2) categorization of antimicrobial drugs based upon the importance of the drug for human medicine and upon which preapproval 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 the animal species treated with the drug 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.

The Framework Document noted that monitoring thresholds also would 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 drug prior to approval, and the threshold could 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 could implement mitigation actions to address the loss of susceptibility or the increasing resistance trend. According to the concepts described in the Framework Document, if mitigation actions were found to be unsuccessful, and resistance levels exceeded the resistance threshold, withdrawal of the approval of the drug for the use(s) of concern would be warranted.

The discussion paper, which is the subject of this notice of availability, further describes an approach for establishing thresholds intended to limit the emergence and spread of antimicrobial resistance in human pathogens attributed to antimicrobial drug use in food-producing animals. The discussion paper attempts to describe the possible complexities of this approach to establishing thresholds in order to encourage discussion before, during, and after the January public meeting mentioned above. A notice of the public meeting was announced in the **Federal Register** of September 26, 2000 (65 FR 57820).

The discussion paper discusses the use of two types of thresholds, a human health threshold and a resistance-in-animals threshold. The human health threshold represents the level at which there is no longer a reasonable certainty of no harm to human health associated