## 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.*

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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