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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiological Safety of Drug Residues in Food; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) will sponsor a workshop entitled "Microbiological Safety of Drug Residues in Food." The workshop will discuss the use of model systems to establish acceptable daily intakes (ADI's) for antimicrobial drug residues in food. The workshop will focus on human consumption of new animal drug residues in food and their direct effects on human intestinal microflora.

The document 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) will not be discussed at this workshop. Information about workshops on the framework document will be announced in a future **Federal Register** notice, CVM update(s), and on CVM's Internet home page, at "<http://www.fda.gov/cvm/fda/mappgs/antitoc.html>".

Date and Time: The workshop will be held on Monday and Tuesday, September 20 to 21, 1999, from 8 a.m to 6 p.m. on Monday and from 8 a.m. to 2 p.m. on Tuesday.

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

Contact: Lynda W. Cowatch, Center for Veterinary Medicine (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5281.

Registration: The registration for the workshop is free. However, registration is required. For additional information and a registration form, please contact Lynda W. Cowatch at the above

address. A registration form is also available on the CVM home page at “<http://www.fda.gov/cvm/fda/mappqs/registration.html>”.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1996 (61 FR 3043), CVM published a notice of availability of a guidance document entitled “Microbiological Testing of Antimicrobial Drug Residues in Food.” This guidance document defines when antimicrobial drugs would be exempt from additional microbiological testing and when additional testing may be necessary to establish the safety of antimicrobial drug residues in food. The document also establishes 1.5 milligrams/person/day as the ADI of microbiologically active residues that would be allowed in food without additional microbiological testing. CVM also expressed the intention of validating model systems that could be used to evaluate the effect of low levels of antimicrobial drugs on the human intestinal microflora.

In 1995 and 1996, CVM initiated research to validate an in vitro and an in vivo model system that could be used to set ADI’s for antimicrobial drug residues in food based on perturbations of the human intestinal microflora. The results of this research will be presented at the September workshop. In addition, other methods for determining ADI’s for antimicrobial residues used internationally and in Europe will be presented and discussed.

Based on the information presented and discussed at the workshop, CVM intends to reevaluate its guidance document for testing microbiological effects of antimicrobial residues on the human intestinal microflora.

Dated: 8/17/99

August 17, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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