

ORGANIZATION: For AMS, members of the Microbiology Laboratory, USDA, AMS, Eastern Laboratory will perform the analyses, and the Laboratory Director will supervise them. The laboratory analysis will be performed at:

USDA, AMS, Science & Technology
National Science Laboratory
801 Summit Crossing Place, Suite B
Gastonia, North Carolina 28054

AMS contact: Laboratory Director
Phone: 704-867-3873
FAX: 704-853-2800

The FDA office responsible for reviewing the human food safety aspects of new animal drugs is the Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Human Food Safety. This office is located at:

Center for Veterinary Medicine
Division of Human Food Safety (HFV-150)
7500 Standish Place
Rockville, MD 20855

FDA contact: Director, Division of Human Food Safety (HFV-150)
Office of New Animal Drug Evaluation
Center for Veterinary Medicine
Phone: (301) 827-5282
FAX: (301) 827-2298

RESPONSIBILITIES:

A. FDA agrees to:

1. Inform sponsors of new antimicrobial animal drugs that the AMS laboratory is capable of evaluating the effects of those drugs on the FSIS detection tests, and that AMS's role is limited to its evaluation of the effects of new antimicrobial drugs on FSIS detection tests.
2. Inform sponsors of AMS's requirement for:
 - a. drug free tissues for control and fortification purposes;
 - b. tissues that contain the incurred drug;
 - c. sufficient chemically characterized drug standard of the same grade as that used in the manufacture of the drug article; and
 - d. the following information about the drug product: chemical name, trade name, active ingredients, dosage form, dose(s) for use in the animal, manufacturing site, lot number or batch number if relevant, drug storage information, packaging information, storage stability and conditions affecting stability, and material safety data sheets.