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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[FDA 225-03-7000]

**Memorandum of Understanding Between the Food and Drug Administration and Agricultural Marketing Service, United States Department of Agriculture**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and Agricultural Marketing Service, United States Department of Agriculture. The purpose of the MOU is to ensure that sponsors of new antimicrobial animal drugs have access to an effective means for evaluating the effects of their drugs on current Food Safety and Inspection Service detection tests.

**DATES:** The agreement became effective January 23, 2003.

**FOR FURTHER INFORMATION CONTACT:** Valerie Reeves, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6973.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108 (c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

BKG1

Dated: 11/21/03  
November 21, 2003.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[INSERT MOU]

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

  
*Joanne*

**MEMORANDUM OF UNDERSTANDING**

Between the  
Agricultural Marketing Service  
United States Department of Agriculture  
and the  
Food and Drug Administration  
United States Department of Health and Human Services

**NAME OF PROJECT:** Determination of the Reactivity of New Animal Drugs in Food Safety and Inspection Service (FSIS) Antimicrobial Detection Tests.

**OBJECTIVE:** The objective of this Memorandum of Understanding (MOU) is to ensure that sponsors of new antimicrobial animal drugs have access to an effective means for evaluating the effects of their drugs on current FSIS detection tests.

FSIS conducts screening and confirmation assays, based on microbial growth inhibition, to detect antimicrobial drug residues in animal tissue used for human food. These assays must be sufficiently reliable because they are important for ensuring food safety. However, new antimicrobial drugs have the potential to interfere with the current assays and FSIS's ability to correctly interpret the results. In addition to FSIS and CVM, manufacturers of antimicrobial animal drugs have an interest in avoiding such interference, particularly when interference causes a test to indicate a false positive. For these reasons, the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) requests that sponsors evaluate the effect of the antimicrobial new animal drugs on the residue detection tests FSIS commonly uses. This information is used in creating strategies to assure the continued reliability of the tests used to monitor food safety.

In FDA's experience, companies that sponsor new animal drugs often do not have ready access to laboratories that can properly evaluate the effects of their drugs on current FSIS detection tests. The Science and Technology Programs of the U.S. Department of Agriculture, Agricultural Marketing Service (AMS), has the ability to perform the necessary evaluation on a fee for service basis. Therefore, FDA and AMS, through this MOU, are agreeing to make that service available to drug sponsors.

**EFFECTIVE DATE:** Date of final signature.

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.

3. Consider AMS's expertise in evaluating the effects of new antimicrobial animal drugs on FSIS detection tests.
4. If requested by the sponsor, review and comment on the tissues and drug levels proposed to be tested.

B. AMS agrees to:

1. Provide an analytical laboratory capable of performing the analysis specified in the FDA/FSIS protocol "*Determination of the Reactivity of New Animal Drugs in FSIS Antimicrobial Detection Tests*" and described in the *Microbiology Laboratory Guidebook (MLG) 3rd edition, 1998, Chapter 33, Sections 33.26-33.27; 33.36-33.363; 33.55-33.57; and Chapter 34.*
2. Conform its basic protocol outline for testing to the specifications in the FDA/FSIS protocol "*Determination of the Reactivity of New Animal Drugs in FSIS Antimicrobial Detection Tests.*"
3. Send the final report of its analytical work to the drug's sponsor.
4. Include in its final report to the drug sponsor the following information:
  - a. drug concentrations tested;
  - b. buffers used for testing;
  - c. tissues tested, specific controls, and fortified and incurred samples;
  - d. tissue preparation or extraction procedure;
  - e. screening tests used; and
  - f. screening test and 7-plate bioassay results for buffer, fortified, and incurred samples, organized by tissue and screening test.
5. Communicate directly with sponsors in regard to the testing of the sponsors' drugs and refer other communications regarding the drug approval process to FDA.

C. It is mutually agreed that:

1. This MOU provides sponsors with one means of evaluating the effects of new antimicrobial animal drugs on the FSIS detection tests, and sponsors retain their discretion in providing this requested information.
2. FDA is not bound by any positions AMS may take as a result of its analysis of a new animal drug pursuant to this MOU. FDA will consider the information provided by AMS as specified in this MOU, but its decisions are independent.
3. Except as otherwise required by law, AMS is not bound by any positions FDA may take as a result of FDA's evaluation of a new animal drug.
4. FDA and AMS will continue to cooperate on improvement of testing protocols as necessary.

BASIS OF COOPERATION/FUNDING:

This MOU defines in general terms the basis on which the parties concerned will cooperate, and does not constitute a financial obligation to serve as a basis for expenditures. Each party will handle and expend its own funds.

Any and all expenditures from Federal funds in the Department of Agriculture made in conformity with the plans outlined in the MOU must be in accord with Department rules and regulations and in each instance based upon appropriate finance papers. Expenditures made by any other cooperator will be in accord with its rules and regulations.

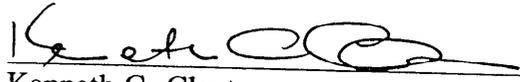
The responsibilities assumed by the cooperating parties under this Memorandum of Understanding are contingent upon funds being available from which expenditures legally may be met.

DURATION:

This agreement shall continue in force indefinitely. It may be amended or terminated by mutual consent of the parties in writing. It may be terminated by either party upon 30 days' notice in writing to the other party.

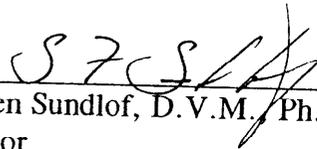
This agreement is hereby approved for the Agricultural Marketing Service.

On 1/23/03  
(Date)

  
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Kenneth C. Clayton  
Associate Administrator  
Agricultural Marketing Service

This agreement is hereby approved for the Food and Drug Administration.

On 1/13/03  
(Date)

  
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Stephen Sundlof, D.V.M., Ph.D.  
Director  
Center for Veterinary Medicine  
Food and Drug Administration