

225-03-7000

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.