

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.