GENERAL REVIEW AND ENFORCEMENT POLICIES

USE OF FOREIGN NON-CLINICAL AND CLINICAL DATA IN AN NADA

1. Purpose:

This guide establishes the Center's policy on accepting data developed in foreign countries to support the safety and effectiveness of new animal drug applications.

2. Submission of Data:

All foreign data pertinent to evaluation of both safety and effectiveness must be submitted in the new animal drug application as provide for in 21 CFR 514.1(b)(8)(iv). These data must be submitted if available to the applicant from investigations or commercial marketing outside the United States and must be submitted whether favorable or unfavorable.

3. Standards with which Data Must Comply:

a. Non-clinical and clinical data from foreign countries must meet the following standards to be accepted as a basis of approval:

(1) Non-clinical Laboratory Studies. A non-clinical laboratory study is defined as "any in vivo or in vitro experiment in which a test article is studied prospectively in a test system under laboratory conditions to determine its safety." This term does not include clinical studies or field trials in animals. Satisfactory foreign studies may be used to complete full NADA requirements for non-clinical data for safety. All non-clinical laboratory studies submitted to support the safety of a new animal drug must comply with the good laboratory practice regulations in 21 CFR 58.

(2) Clinical Data (Field Trials). Clinical data (field trials) for safety and effectiveness must be conducted by personnel qualified by scientific training and experience to conduct such tests and include all the information required by 21 CFR 514.1(b)(8). All clinical (field) or other (laboratory scale) investigations submitted from foreign countries to support effectiveness must be well-controlled unless waived as provided for in 21 CFR 514.111(a)(5). Clinical studies should be evaluated with respect to the guideline Monitoring of Clinical Investigations.

b. Because of differences in animal breeds, nutrition, husbandry practices, and disease, foreign clinical trials are not normally acceptable as fulfilling complete NADA requirements for effectiveness. They may, however, serve as either pivotal or corroborative studies, and thus may be used as at least a portion of the basis of approval. At least one pivotal effectiveness study must be conducted in the United States. The

sponsor should document the reason why United States clinical studies (field trials) are not practical or necessary at the time of INAD or NADA submission, and submit a written request for waiver of U.S. clinical studies to the Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

4. Determination of Validity:

For either non-clinical or clinical studies, the FDA must be able to consider the data valid without the need for an on-site inspection by FDA, or if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. In the case of a non-clinical study, there shall be a statement that the study was conducted in compliance with Good Laboratory Practice regulations in Part 58, or if the study was not conducted in compliance with those regulations, a statement of the reason for the noncompliance.