ANIMAL DRUG APPLICATIONS EXPEDITED REVIEW GUIDELINE

1. Purpose:

This guide provides criteria and procedures for the classification and review of new animal drug applications (NADAs) submitted to the Agency for approval. Under the Center for Veterinary Medicine (CVM) Expedited Review Status (ERS), certain products classified as important advances in animal health will receive priority review commencing at the Investigational New Animal Drug (INAD) stage, but with no diminished standards for data quality or evaluation.

2. Background:

Under the expedited review program, submissions to support a qualified product will be afforded a more rapid and prioritized review from that normally defined for routine applications, in both the INAD and NADA review processes. The drug classification definitions which appear in this section were devised to provide a convenient way of describing INADs or NADAs submitted for priority review.

The classification definitions should be used by a drug sponsor to classify the drug. If the proposed drug product meets the criteria for classification for ERS, then the sponsor may request that CVM give the drug priority review.

3. Classification Definitions:

a. Chemical Types:

Type 1 - New molecular entity - i.e., the active moiety is not yet marketed in the United States for use in the animal species/class by any drug manufacturer, either as single entity or as part of a combination product.

Type 2 - New salt, ester, or derivative - i.e., the active moiety is marketed in the United States for use in the animal species by the same or another manufacturer but the particular salt, ester or derivative is not yet marketed in the United States by any drug manufacturer either as a single entity or as part of a combination product.

Type 3 - New dosage form or formulation - i.e., the compound is marketed in the United States for use in the animal species by the same or another manufacturer, but the particular dosage form or formulation is not.

Type 4 - New combination - i.e. , a product which contains two or more compounds, none

of which have been previously marketed singly in an animal drug product by any manufacturer in the United States.

Type 5 - Already marketed animal drug product - i.e., the product duplicates a drug product (the same active moiety, same salt, same formulation, or same combination) already marketed in the United States by another sponsor.

b. Therapeutic Potential:

Type A - Important therapeutic gain - i.e., drug is indicated for a life-threatening or severely debilitating disease, and no satisfactory alternative therapy is provided by any marketed product.

Type B - Modest therapeutic gain - i.e., drug has a modest advantage over other available marketed drugs - e.g., greater convenience in administration, elimination of an annoying but not dangerous adverse reaction, useful in specific subpopulation of those with disease (e.g., those not responding to or intolerant of other available drugs).

Type C - Little or no therapeutic gain - i.e., drug essentially duplicates in medical importance and therapeutic usage one or more already marketed drugs.

Type D - Special situation - i.e., drug has decreased safety or effectiveness compared with alternative marketed drugs, but also has some compensating feature (e.g., provides treatment for individual animals who do not respond to or are intolerant of alternative drugs).

4. Responsibilities and Procedures:

The sponsor shall submit to the appropriate Division Director in the Office of New Animal Drug Evaluation, Center for Veterinary Medicine, a written request for review under ERS with adequate documentation that demonstrates the drug is eligible for priority review. This documentation should include sufficient data and information to permit the classification of the therapeutic gain in 3(b) above. A decision to apply ERS may be deferred until sufficient information is provided.

The drug must usually receive classification as a Type 1 or Type 4 chemical having therapeutic potential A to be assigned expedited review status. However, products classified as chemical Type 2, 3, or 5 with therapeutic potential A may be considered for ERS. If data at any time do not support the designated classification, the file will revert to normal processing procedures and the sponsor will be notified.

The decision to apply the ERS is made by the Division assigned the application and the Director, Office of New Animal Drug Evaluation (NADE). CVM will inform the sponsor of its decision to

grant ERS eligibility within 60 days of CVM receipt of the NADA. If substantial data are also submitted at the time of the request, the time for completion of the data review will be 90 days from the date of notification of eligibility.

a. Procedures for making the determination as to whether a drug product is eligible for inclusion may follow one of several alternatives.

(1) The determination of ERS should be made as early as possible in the drug development and review process.

(2) If an INAD has not been previously established for the drug, the sponsor should request ERS as well as simultaneously establishing an INAD. CVM will inform the sponsor of its decision concerning the eligibility of the product within 60 days of receipt of the submission.

(3) A second situation will involve the case where an INAD has been previously established. In such a case, the sponsor should simply request expedited review status. The Center will respond within 60 days.

(4) In the absence of a sponsor's petition, the Director, ONADE (HFV-100) may make the determination that an animal drug product is eligible for ERS classification. In such cases, the sponsor will be notified of the ERS classification in the usual fashion.

b. Once the decision has been made to classify the drug product in ERS, the objective is to demonstrate as rapidly as possible that the product is safe and effective and the manufacturing controls are adequate.

Any product classified ERS may be withdrawn from expedited review if information is received during the data generation that refutes the initial classification or if another product is approved for the same claim. This will be brought to the attention of the Director, ONADE and a decision made as to whether or not to terminate the ERS. If the ERS is terminated, the sponsor will be notified and the file handled under standard procedures.