GENERAL REVIEW AND ENFORCEMENT POLICIES

REQUIREMENTS FOR IMPORTATION OF INVESTIGATIONAL NEW ANIMAL DRUGS

1. Purpose:

This guide describes the requirements for importation of new animal drugs into the United States. For the purposes of this document, the imports may be divided into three categories, classed according to requirements under 511.1(a) and 511.1(b).

2. Requirements for Importation of New Animal Drugs for Non-Clinical Investigations Under 511.1(a):

A new animal drug (or feed containing the drug) intended for use in non-clinical investigations under 511.1 (a) may be imported if the following conditions are met:

(1) The drug is intended solely for tests in vitro or in animals used only for laboratory research purposes.

(2) It is labeled in accord with 511.1(a).

(3) All other conditions specified in 511.1(a) are met.

These conditions also apply to importation of bulk drug substances for use in the manufacture of investigational new animal drugs intended for non-clinical investigations, except that the following labeling statement should be used, as described under 21 CFR 201.122:

"Caution: For manufacturing, processing, or repacking in the preparation of an animal drug limited by Federal law to investigational use."

3. Requirements for Importation of New Animal Drugs for Clinical Investigations Under 511.1(b)--**Shipment Directly to a Scientific Institution.**

New animal drugs intended for use in clinical investigations under 511.1(b) may be imported if all the conditions of 511.1(b) are met. The regulations under 511.1(b)(9) specify particular

conditions that must be met, depending on whether the drug will be shipped to a scientific institution or to some other sponsor or manufacturer as the ultimate consignee. The difference is that, in the latter case, prior notification of the agency of the intention to import the drug is required.

A pharmaceutical company is not a "scientific institution" for purposes of 511.1(b)(9).

For Importation and Shipment Directly to a Scientific Institution, A Drug May be Imported if the Following Conditions are Met:

a. Prior to shipment of the new animal drug for clinical tests in animals, the scientific institution has submitted a statement as sponsor of the investigation (that is, has submitted a "Notice of Claimed Investigational Exemption for a New Animal Drug" containing a signed statement with the information specified in 511.1(b)(4)).

b. All other conditions specified in 511.1(b) are met. In particular, if the drug is intended for use in a food-producing animal, the requirements for authorization specified in 511.1(b)(5) must be met.

4. **Requirements for Importation of Investigational New Animal Drugs Intended for Use in Clinical Investigations--Shipment to Consignees other than a Scientific Institution.**

New animal drugs intended for use in clinical investigations under 511.1(b) may be imported if all the conditions of 511.1(b) are met. The regulations under 511.1(b)(9) specify particular conditions that must be met, depending on whether the drug will be shipped to a scientific institution or to some other sponsor or manufacturer as the ultimate consignee. The difference is that, in the latter case, prior notification of the agency of the intention to import the drug is required.

These conditions also apply to importation of bulk drug substances for use in the manufacture of investigational new animal drugs intended for clinical investigations, except that the following labeling statement should be used, as described under 21 CFR 201.122:

> "Caution: For manufacturing, processing, or repacking in the preparation of an animal drug limited by Federal law to investigational use."

For Shipment to Sponsors (Consignees) Other than a Scientific Institution. A Drug May be Imported if the Following Conditions are Met:

a. The importer is either an agent of the foreign exporter residing in the United States, or the importer is the ultimate consignee.

b. The importer has, prior to shipment, informed the Food and Drug Administration of the shipment and of his/her intention to import the new animal drug as sponsor in compliance with 511.1(b). (That is, the importer has submitted a "Notice of Claimed Investigational Exemption for a New Animal Drug" containing a signed statement with the information specified in 511.1(b)(4)).

`c. The information contained in the notification of intention to import is complete. Such notices should identify:

(1) The INAD number;

(2) Name of drug;

(3) Proposed use of drug, including species;

(4) Destination of shipment;

(5) Port of entry;

(6) Name and address of distributor, broker or agent through whom the drug or drug substance is to be imported;

(7) Approximate date of entry;

(8) Name and address of foreign manufacturer;

(9) Amount of drug or drug substance to be imported;

(10) For a bulk drug substance, number of dosage units to be manufactured; and

(11) Number of dosage units previously used or manufactured.

d. All other conditions specified in 511.1(b) are met. In particular, if the drug is intended for use in a food-producing animal, the requirements for authorization specified in 511.1(b)(5) must be met.

5. Procedures for Review and Handling of INAD Submissions Related to Imports

Routine INAD procedures, in accord with either 511.1(a) or 511.1(b), apply to submissions discussed under items 2, 3, and 4 (above). For a notification of intention to import as described in 511.1(b)(9) and in item 4.c. (above), the primary review branch shall determine if all conditions have been met and the information as described in Item 4.c. is complete. Such notices are acknowledged by letter to the sponsor, with a copy to the FDA District Office covering the port of entry.