DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 17 1990

Dear Sir or Madam:

This is the sixth in a series of policy letters regarding the implementation of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA), which was signed into law on November 16, 1988.

We are introducing two policy statements (refer to attachment) which address our continuing implementation of the new law. The policy statements are entitled as follows:

1) "Withdrawal Period for Generic Animal Drug Products"

2) "Eligibility of a New Salt or Ester of a Pioneer Animal Drug for an ANADA"

The first policy statement, "Withdrawal Period for Generic Animal Drug Products", is a revision of the policy statement entitled "Withdrawal Period for Generic Drugs" which was issued with our third policy letter dated August 2, 1989. The revised statement replaces the 8-2-89 statement.

We welcome comments and questions from all interested parties. If any changes are made, the revised policy statements will be placed on public display, and a notice of availability will be published in the FEDERAL REGISTER.

Comments on the policy statements may be submitted to:

Dockets Management Branch
HFA-305, Room 4-62
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We will continue to announce the availability of our policy statements regarding the new law.

Sincerely yours,

Richard H. Teske

for Gerald B. Guest, DVM
Director, Center for
Veterinary Medicine

Attachment

1) Withdrawal Period for Generic Animal Drug Products

A generic animal drug product will ordinarily be granted the same withdrawal period as the pioneer product if bioequivalence, using blood level data, is demonstrated. However, if the time for blood concentrations to decline to the limit of detection is longer for the generic product than the reference (pioneer) product, then a tissue residue study may be required.

If bioequivalence is demonstrated using pharmacological or clinical endpoint studies, then the generic sponsor must ordinarily collect tissue residue depletion data to establish the appropriate withdrawal period.

The withdrawal period established in the tissue residue study need not be the same as the withdrawal period for the pioneer drug. If the generic sponsor submits a tissue residue study, and the data indicate that the withdrawal period is longer than for the pioneer product, then the generic product will be given the longer withdrawal time. However, under an abbreviated new animal drug application (ANADA), a generic product will not be assigned a shorter withdrawal period than the pioneer product.

The sponsor may attempt to establish a shorter withdrawal period for the generic product by filing a supplement to the approved ANADA. The supplement will be a Category II supplement, as defined in CVM's policy on supplemental applications. For a Category II supplement, a re-evaluation of the safety (or efficacy) data in the parent application (i.e. pioneer NADA) may be required.

The generic sponsor should use the approved method of analysis in its tissue residue study, even if the approved method has changed since the original approval. If an analytical method other than the approved method of analysis is used, the generic sponsor must provide data comparing the alternate method to the approved method.

2) Eligibility of A New Salt or Ester of a Pioneer Animal Drug for an ANADA

As part of the requirement of an abbreviated new animal drug application (ANADA), the generic sponsor must show that the active ingredient of the proposed generic product is the same as the active ingredient of the reference (pioneer) product. For salts and esters, the "same" active ingredient is interpreted to mean the same salt or ester form of the new animal drug in the finished animal drug product prior to its administration. A product that contains a different salt or ester form of the same drug in the finished animal drug product will be considered to contain a different active ingredient.

Because the Agency considers a different salt or ester to be a different active ingredient, suitability petitions seeking permission to file an ANADA for a different salt or ester from that of the pioneer product can not be approved, unless the petition seeks a change in one active ingredient in a combination product (or in a feed use combination) and the different salt or ester is previously approved or is not a new animal drug as defined by the Federal Food, Drug, and Cosmetic Act. An ANADA seeking approval of a different salt or ester in a product that contains a single new animal drug will not be accepted.