DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, Maryland 20857

April 12, 1990

Dear Sir or Madam:

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

We are introducing the revised Bioequivalence Guideline dated April 12, 1990. The April 12, 1990 Bioequivalence Guideline is a revision of the April 19, 1989 Bioequivalence Guideline, announced in the June 21, 1989 Federal Register as part of the second generic animal drug policy letter. The current Guideline was revised with due consideration given to comments received on the April 19, 1989 Guideline.

Copies of the April 12, 1990 Bioequivalence Guideline may be obtained by contacting:

Industry Information Staff (HfV-12)
Room 7-85
Center for Veterinary Medicine
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(301) 443-4557

We welcome comments on the April 12, 1990 Bioequivalence Guideline from all interested parties. If any changes are made, availability of the revised Guideline will be announced in the Federal Register.

Comments of the Guideline 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 policy letters regarding implementation of the new law.

Sincerely yours,

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

Attachment

NOTE: The April 12, 1990 Bioequivalence Guideline has been updated. The current copy is available from our web site.