SUPPLEMENTAL POLICIES

IDENTIFICATION/PROMOTION OF PRODUCT APPROVAL

Section 301(l) of the Federal Food, Drug, and Cosmetic Act prohibits the use in labeling or advertising of any human drug or device "any representation or suggestion that approval of an application with respect to such drug or device is in effect." There is no such prohibition regarding animal drugs. The Center for Veterinary Medicine (CVM) is not opposed, in principle, to the appearance of such information on labels or labeling of, or in advertisements for, approved new animal drugs. However, all such additions to labels and package labeling must be submitted to CVM as a special DER to the approved new animal drug application. Promotional labeling for all approved products must be submitted for review at the time of initial dissemination. Prescription animal drug advertising must be submitted at the time of initial publication as currently required by 21 CFR 510.300.

1. Purpose:

   This document established CVM policy and provides guidance for reviewing submissions of sponsors interested in voluntarily placing the Food and Drug Administration (FDA) approval information on labels or package labeling or in using it in advertising or other promotional material for approved new animal drugs.

2. Policy:

   CVM will allow information indicating NADA or ANADA approval on labels or labeling, or in advertising for, approved new animal drugs.

3. Labeling Requirements:

   a. Labels and package labeling may be revised and placed into use upon the submission of a special Drug Experience Report.

   b. The label and package labeling may bear only the statement, "NADA#-----, Approved by FDA." This statement should appear on one line only and the entire statement should be of consistent type size, color and contrast. In the event the space on the label does not permit printing of the statement on one line, the statement may appear

on two lines and placed within large bracket, e.g., [NADA#-----, Approved by FDA.] If an ANADA, the label and package labeling may bear only the statement, "ANADA #-----, Approved by FDA."

c. If the NADA or ANADA provides for a product which is manufactured for "private-label" distribution, then all distributor labeling should be similarly revised in keeping with the requirement that all such labeling be identical to sponsor labeling with the exception of Trade Name and Distributor Name. This should be accomplished by including revised labeling for all current distributors with the special drug experience report providing for revised sponsor labeling. If new distributors are subsequently added, their labeling may be submitted in a subsequent drug experience report.

d. For the sake of consistency, the statement should appear at the bottom of the front panel of the label on the immediate container at the bottom of the carton labeling (preferably on the front or main display panel). It should also appear at the very top (beginning) or the very bottom (end) of inserts.

e. In terms of type style, size, color or other means of emphasis, the statement should be no more prominent than the least prominent signal word identifying cautionary information appearing on the label (or the text of such cautionary information if no signal word is used to identify it).

f. The statement must not obscure or otherwise render less conspicuous any necessary information on labels or labeling.

g. The statement may be used in promotional labeling or advertising for approved products.

h. Any additional statements in promotional material may be directed only to the fact of NADA or ANADA approval and may not characterize the basis, nature or impact of the approval either directly as it applies to a particular product or relative to other approved or unapproved products. The availability of a Freedom of Information Summary (summary basis of approval) on file with FDA may be noted in promotional material. The specific section of the Code of Federal Regulations which established the conditions of approval may be cited.