DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 16 2003

NADA 141-203

Marne L. Platt, VMD
Regulatory Affairs Manager
Novartis Animal Health US, Inc.
3200 Northline Avenue
Suite 300
Greensboro, NC 27408

Dear Dr. Platt:

This letter objects to Novartis' dissemination of promotional materials that are in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA's applicable implementing regulations. This letter refers to your submissions for Drug Experience Reports dated August 30 through September 17, 2002, concerning Deramaxx™ tablets, NADA 141-203. We have also received a number of complaints from industry and from veterinarians, including complaints that the letter to veterinarians, issued by Novartis Animal Health on September 9, 2002, contains misleading claims.

The letter to veterinarians contains the statement "*targeting the COX-2 enzyme while sparing the COX-1 enzyme*", and similar statements appear throughout the promotions cited above. As described in 21 C.F.R. § 202.1(e)(6)(vii), a favorable conclusion from nonclinical studies, for which clinical significance has not been demonstrated, should not be presented in a way that suggests the conclusion has clinical significance. Novartis' claim that Deramaxx™ *"targets the COX-2 enzyme while sparing the COX-1 enzyme"* is based upon *in-vitro* studies using cloned canine cyclooxygenase. As stated in the product's approved package insert, "the clinical relevance of this *in vitro* data has not been shown". As 21 C.F.R. § 202.1(e)(3)(i) makes clear, an otherwise misleading statement must include the appropriate qualification in the same part. The appropriate qualification should be included in every part the statement appears to avoid misleading consumers.

The opening paragraph of the letter to veterinarians, which claims the product is the "*first and only...*", and goes on to provide a definition of "*Coxib class drug*", is misleading because it promotes this product as a "new" "Coxib class" product and avoids identifying the product as a NSAID. The term NSAID is used in the letter only in a later paragraph and in reference to other products, i.e., "the older NSAIDs". However, Coxib is a subclass of the NSAID class of drugs and not a separate drug classification. This is

reflected in the approved labeling, which uses the phrase "non-steroidal, anti-inflammatory of the coxib class".

This promotional activity minimizes risks and implies that the product is safer and more effective than other drugs in the same drug class. We are particularly concerned because these specific limitations were thoroughly discussed with HFV-110 during the application review.[1,2] Despite documented verbal assertions that it would not, Novartis has promoted the COX-2 vs. COX-1 selectivity of the product.

You should immediately cease dissemination of these and any other similarly violative promotional pieces. We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA 356V, that you will promote your product only in accord with the labeling provided in the approved application. Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions you may contact us at (301) 827-6642.

Sincerely yours,

Lynn O. Post, D.V.M., Ph.D.
Acting Director
Division of Surveillance
Center for Veterinary Medicine