DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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SP 01P-0139/CP 1

DEC 19 2001

Pierre Gadbois d.m.v.
Manager, Regulatory Affairs
Vetoquinol N.-A. Inc.
2000 chemin Georges
Lavaltrie, Quebec, Canada, J0K 1H0

Dear Dr. Gadbois:

We refer to your suitability petition filed March 21, 2001, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a dosage form and strength that differ from those of an approved new animal drug. The proposed pioneer product is Lloyd's PrednisTab ® (prednisolone tablets) which is intended for use in dogs (NADA 140-921).

Your proposed product differs from the pioneer product in dosage form and strength. The pioneer product is a tablet, containing 5 or 20 mg prednisolone per tablet; whereas your proposed product is a palatable paste containing 5 or 25 mg prednisolone per milliliter, and delivered from a syringe. The dosage of active ingredient per pound of body weight would be the same.

Changes in dosage form and strength are two of the five variances in the pioneer product which can be sought through a suitability petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed dosage form and strength.

Because we have determined that such investigations are not necessary, your suitability petition is approved. Approval of the suitability petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA.

In addition to other information in your ANADA application, such as information to demonstrate bioequivalence between the pioneer and generic products, we will require you to conduct a palatability study with the generic product. Palatability is not directly related to effectiveness. Under section 512(n)(1)(D) of the FFDCA, palatability studies may be required in an ANADA with regard to a change in dosage form. We recommend that you submit protocols for our evaluation before initiating any studies.

We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved

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labeling for the pioneer, with certain allowable differences, such as directions for administration of the paste.

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug and Quality Control Staff, (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours, 12/18/01

Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine