



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SP 01P-0385/CP 1

FEB 14 2002

Anne Nallen
Regulatory Affairs
Cross Vetpharm Group Ltd.
Broomhill Road
Tallaght
Dublin 24
IRELAND

Dear Ms. Nallen:

We refer to your suitability petition filed September 4, 2001, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs from an approved new animal drug. The proposed pioneer product is Boehringer Ingelheim Vetmedica's Medamycin[®]-100 (oxytetracycline hydrochloride) 100 mg/mL injection, which is intended for use in beef cattle, beef calves, non-lactating dairy cattle and dairy calves (NADA 108-963). Your proposed product would contain 300 mg/mL oxytetracycline.

Your proposed product differs from the pioneer product in strength. The pioneer product contains 100 mg/mL oxytetracycline hydrochloride; whereas your proposed product would contain 300 mg/mL oxytetracycline base (as dihydrate). Your proposed product would deliver 3-5 mg oxytetracycline (as a magnesium complex) per pound of body weight, by intravenous injection, as does the pioneer.

A change in strength is one of the five variances in the pioneer product which can be sought through a suitability petition under section 512(n)(3) of the FFDCA, as amended. Pursuant to that provision, we are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed strength. We conclude that your petition must be denied because investigations must be conducted to show the safety of your product. The increase in strength of oxytetracycline would necessitate evaluation of the target animal safety of the proposed product. A target animal safety examination would include examining the potential of the higher strength of oxytetracycline to produce severe adverse effects, including collapse and death in calves and cattle, when administered by intravenous injection.

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You indicate in your petition that you would provide the results of animal studies supporting safety issues for the more highly concentrated generic product. You may do this by submitting a hybrid application, which combines the elements of an ANADA and an NADA.

This is described in our Seventh GADPTRA Policy Letter, dated March 20, 1991, and was announced in the Federal Register on April 15, 1991 (56 FR 15083). The exact requirements of a hybrid application depend on the product for which the application is submitted and may include a bioequivalence study, a tissue residue depletion study, and any additional studies required for approval of the application. We recommend that you discuss with us the studies we believe will be necessary and that you submit protocols for our review before beginning any *in vivo* studies.

If you disagree with our denial of your suitability petition, you may petition for reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Such petition should be submitted in accordance with § 10.20 in the format outlined in § 10.33. The petition must be based solely on the information and views contained in your original petition. The petition for reconsideration should be submitted no later than 30 days after the date of this denial of the suitability petition and must be filed with the Dockets Management Branch, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to docket number 01P-0385 in any submission regarding this original suitability petition.

If there is additional information not included as part of your original submission that you would like the agency to consider, you should submit a new petition under § 10.30 and include all necessary information to the Dockets Management Branch at the address noted above.

This action in response to your suitability petition does not alter the requirements for approval of a new animal drug, nor assure approval of the new animal drug.

If you wish to submit a hybrid application, we will conduct a definitive labeling review when the application is received. The labeling of your product must be identical to that of the pioneer product, except for certain allowable changes, such as manufacturers name, tradename, and any changes supported by safety or effectiveness studies submitted in the hybrid application.

If you wish to discuss our additional requirements for a hybrid application, you may call Dr. Lonnie W. Luther, Chief, Generic Animal Drug Team, (301) 827-0209.

Sincerely yours,



Claire M. Lathers, Ph.D., F.C.P.
Director

Office of New Animal Drug Evaluation
Center for Veterinary Medicine