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**Boehringer
Ingelheim**

BOEHRINGER INGELHEIM ANIMAL HEALTH, INC.

60026

November 17, 1998

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine (HFV-1)
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

**MF 3577
NOPTRACIN® MD-50
BACITRACIN METHYLENE DISALICYLATE
TYPE A MEDICATED ARTICLES
GENERAL CORRESPONDENCE
RE: 21 CFR 558.15
AMENDMENT TO LETTER DATED SEPTEMBER 18, 1998**

Dear Dr. Sundlof:

We are amending our September 18, 1998 letter that responded to your letter dated July 29, 1998 pertaining to the 21 CFR 558.15 listing of Boehringer Ingelheim Vetmedica, Inc.'s (BIVI) product, bacitracin methylene disalicylate Type A medicated article. For ready reference, a copy of the aforementioned letter is attached.

I, Donald A. Gable, Manager, Pharmaceutical Regulatory Affairs, BIVI, truly believe I can certify to the best of my knowledge that NOPTRACIN® MD-50 (bacitracin methylene disalicylate) Type A Medicated Article was an animal drug product approved by the Food and Drug Administration for the NOPCO CHEMICAL COMPANY. As explained in my September 18, 1998 letter, ownership of this approved Type A Medicated Article has changed several times prior to ownership by BIVI. Further, I truly believe that NOPTRACIN® MD-50 Type A Medicated Article was approved as the subject of an Antibiotic Form 6 with the NOPCO CHEMICAL COMPANY as the sponsor (date of approval not known, but probably in the 1960s). The Antibiotic Form 6 approval was under the section 507 provisions of the Federal Food, Drug, and Cosmetic Act during this time period. Data submitted under section 507 was not proprietary. Also, a Master File (MF 3577) was approved for NOPTRACIN® MD-50 Type A Medicated Article on February 25, 1974. The Diamond Shamrock Chemical Company, a company that acquired NOPCO CHEMICAL COMPANY, filed MF 3577. The aforementioned MF became the submission file for exchange of communications between the Diamond Shamrock Chemical Company and the CVM (then BVM). Likewise, Fermenta Animal Health Company and BIVI have corresponded with CVM through MF 3577. NOPTRACIN® MD-50 Type A Medicated Article was approved for use in chickens, turkeys, swine and cattle for the indications for use itemized in 21 CFR 558.78.

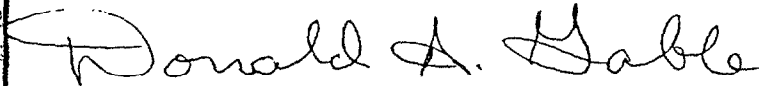
As stated in my September 18, 1998 letter, the administrative record supports a conclusion that NOPTRACIN® MD-50 ANTIBIOTIC FEED SUPPLEMENT, a medicated premix containing bacitracin methylene disalicylate, is covered by the marketing provisions of section 108 of the Animal Drug Amendments of 1968, P. L. 90-399.

Re-iteration from my September 18, 1998 letter: As requested by your letter dated July 29, 1998, the undersigned includes the following statement in this letter: "I certify that all the statements made in this letter are true and complete to the best of my knowledge and ability and that the attached new animal drug label is a true and complete copy. I understand that, as with any other statements provided to the Food and Drug Administration, willfully making a false certification is a criminal offense under U.S. Code, Title 18, Sec. 1001."

Finally, we refer to our pending submission to MF 3577 that was dated July 16, 1996 (from the undersigned to Dr. Andrew Beaulieu). This submission involves a joint discussion that included an additional animal drug sponsor.

We look forward to your response. If I may be of assistance, please call me at (913) 380-3025.

Sincerely,



Donald A. Gable, D.V.M.
Manager, Pharmaceutical Regulatory Affairs
Boehringer Ingelheim Vetmedica, Inc.

Attachment: Letter dated September 18, 1998

Desk Copy: Dr. Dianne McRae (HFV-102)

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