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PURGED BK

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

January 12, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 24

Allen Petro
Owner
Ana-Tech
714 - 30th Street
Monroe, Wisconsin 53566

Dear Mr. Petro:

An inspection of your firm at Monroe, WI, on May 31, 2000, by an investigator from the Food and Drug Administration (FDA) found that you are manufacturing and distributing an adulterated animal drug in violation of Sections 501(a)(5) and 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The product is also misbranded in violation of Section 502(o) of the Act.

The product "BLU-HOOF Topical" meets the definition of a new animal drug as defined by Section 201(v) of the Act. Since you do not have a new animal drug application on file with the FDA, the product is considered unsafe within the meaning of Section 512 of the Act. Any product considered unsafe within the meaning of Section 512 of the Act is adulterated within the meaning of Section 501(a)(5) of the Act. "BLU-HOOF Topical" is also adulterated within the meaning of Section 501(a)(2)(B) of the Act in that it was not manufactured in accordance with Current Good Manufacturing Practice regulations as codified in Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). In addition, the product is also misbranded within the meaning of Section 502(o) of the Act in that it was not manufactured at a facility that is registered with FDA nor has your firm listed their products in accordance with Section 510 of the Act. The registration and listing forms, FDA 2656 and 2656e, are available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>. Select human drugs.

For your information, we have reviewed the labels submitted by the investigator and have the following comments. The name "ANA-KETO" implies that it is intended for the treatment and/or prevention of ketosis in dairy cattle. Products for the treatment or prevention of ketosis are drugs. At this time the Center for Veterinary Medicine (CVM) considers this product to be a drug without adequate

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directions for use. The name cannot imply any therapeutic intent unless you intend to market the product as a drug.

The name "CAL-B4" implies that it is intended for the treatment and/or prevention of hypocalcemia in dairy cattle and may even imply an intent for prevention of milk fever. Products for the prevention and/or treatment of hypocalcemia and milk fever are drugs. At this time the CVM considers this product to be a drug without adequate directions for use. The name cannot imply any therapeutic intent unless you intend to market the product as a drug. In addition, selenium must be removed from the product unless it complies with 21 CFR 573.920(g), copy enclosed.

The label for "X-IT(W)" contains the statement "If symptoms persist after 7 days use X-IT in conjunction with antibiotics." This clearly implies the product is a drug. If the references to symptoms and antibiotics are removed, the product could be marketed as an iodine supplement.

The label for "Day One" states "source of naturally occurring microorganisms" instead of the accepted American Feed Control Officials' (AAFCO) statement: "source of live (viable) naturally occurring organisms." In addition, the "Day One" product refers to "stress conditions" on its label without further explanation or clarification. Not all guarantees are in colony-forming units (CFUs) per gram or pound as specified in the AAFCO publication. One product, "Max Cap 600," contains no measure of the guarantee. Two other products, "Pro Cap I" and "Direct Action," contain the number of CFUs per gelcap. Two of the products, "Pro Lyte" and "Top Dairy," contain the number of CFUs per ounce. The feeding directions for these two products were by the ounce. The remaining direct fed microbial products declare the CFUs per ounce but the feeding directions are in pounds. Information on the AAFCO publication can be obtained at the following web site: <http://www.aafco.org>.

All the direct fed microbial labels should be checked for correct nomenclature and spelling, e.g., streptococcus instead of enterococcus, diacetylactis instead of diacytelactis, thermophilus instead of thermophilum. In addition, your firm needs to have a verifiable method for testing the veracity of the guarantees on each of the product labels on the direct fed microbials as referenced in our Compliance Policy Guide, Section 689.100, copy enclosed.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

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You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Timothy Philips at the address on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

RPS/ccl
SLY

Enclosures: 21 CFR 211
21 CFR 573.920
CGP 689.100