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

March 22, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 42

Brian C. Langdon
President
New Decade Laboratories, Inc.
821 Third Street
Farmington, Minnesota 55024

Dear Mr. Langdon:

During an inspection of your veterinary drug manufacturing facility located at Farmington, MN, conducted on February 12, 14 and 27, 2001, our investigator found significant deviations from the current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). Such deviations cause veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found that:

- manufacturing and cleaning processes have not been validated;
- components, drug product containers, and finished drug products are not properly quarantined and tested;
- batch records lack complete and accurate information concerning the production and control of drug products;
- specifications for drug products are incomplete;
- drug products have been accepted and released even though they failed to meet specifications; and
- the stability testing program does not support the 2-year expiration date placed on drug products.

The above-noted deficiencies, and others, were cited on an FDA-483 (copy attached) issued to your firm on February 27, 2001.

Page Two

Brian C. Langdon
March 22, 2001

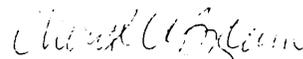
The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as president to ensure that your establishment is in compliance with all requirements of the Federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Please 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 and to prevent their recurrence. 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.

Your reply should be sent to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,


Cheryl A. Bigham
Acting Director
Minneapolis District

TGP/ccl
A4

Enclosure: FDA-483, 2/27/01

xc: Steven L. Granneman
Production Manager
New Decade Laboratories, Inc.
821 Third Street
Farmington, MN 55024