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

PURGED

September 11, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 50

Frank McDowell
General Manager
New Vision Co-op
1301 County Road 5, P.O. Box 877
Worthington, Minnesota 56187

Dear Mr. McDowell:

An inspection on July 10, 2000, of your medicated feed mill located at Jeffers, MN. conducted by an investigator from the Minnesota Department of Agriculture on behalf of the Food and Drug Administration found significant deviations from current Good Manufacturing Practice (GMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulation, Part 225 (21 CFR 225)]. Such deviations cause medicated feeds being manufactured at the 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 revealed the following deviations:

1. The bulk liquid scale is inoperable and has been for several years. All scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently as may be necessary to insure their accuracy, 21 CFR 225.30(b)(4).
2. Your bulk liquid scale is inoperable. This makes it impossible to consistently produce a medicated feed of intended potency, safety and purity. All equipment shall possess the capability to produce a medicated feed of intended potency, safety and purity, 21 CFR 225.30(b)(1).
3. Your drug inventory records have the amount used and the theoretical balance but do not record the actual balance. Drug inventory shall be maintained of each lot or shipment of drug by means of a daily comparison

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of the actual amount of drug used with the theoretical drug usage. Any significant discrepancy shall be investigated and corrective action taken, 21 CFR 225.42(b)(7).

4. No records are available demonstrating that any assays have been performed. For feeds requiring a medicated feed mill license for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods at periodic intervals during the calendar year, 21 CFR 225.58(b)(1).
5. No originals or copies of assays are maintained on the premises. The originals or copies of all results of assays, including those from state feed control officials and any other governmental agency, shall be maintained on the premises for a period of not less than one year after distribution of the medicated feed, 21 CFR 225.58(c).

A review of the files indicates your mill license was last approved July 11, 1997. 21 CFR 207.20 and 21 require you to register once a year. The mill license regulation and an application are available online at www.fda.gov/cvm.

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

You should take prompt action to correct these GMP violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these GMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your mill license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

This letter constitutes official notification under the law. Based on the result of the July 10, 2000, inspection, evaluated together with the evidence before FDA when the mill license was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed are inadequate to assure and preserve the identity, strength, quality and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct

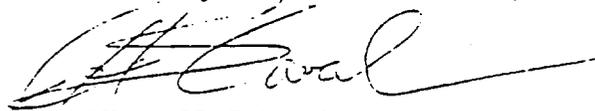
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the GMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,



Albert H. Schwab
Acting Director
Minneapolis District

RPS/ccj

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