



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

May 2, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Richard C. Nelson
President
Nelson and Sons, Inc.
118 West 4800 South
Murray, Utah 84157

Ref. #: DEN-00-25

Dear Mr. Nelson:

Food and Drug Investigator Wayne W. Grundstrom conducted an investigation of your medicated feed mill on November 4 & 8, 1999. Significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds [Title 21 Code of Federal Regulations, part 225 (21 CFR 225)] were found. Such deviations cause feeds being 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 inspection also determined that one lot of medicated feed, manufactured by you, is adulterated within the meaning of 501(a)(6).

Nelson & Sons Silver Cup Fish Feed / Silver Cup Medicated, batch #343090799, manufactured at your firm on September 7, 1999, was labeled with a recommended feeding rate of 1% body weight per day, this rate of feed for the amount of drug in the feed would be double the approved dosage for this medicated feed.

Our investigation found the following CGMP deficiencies:

- 1) Two different lots of fish pellets, medicated with sulfadimethoxine and ormetoprim, were found by the firm to be out of specification for potency at 57% and 74%. No investigations were conducted to determine the causes and no corrective actions were taken to prevent recurrence,
- 2) Silver Cup Medicated feed, containing sulfadimethoxine and ormetoprim, was labeled with feeding levels at twice the allowed level,

- 3) Drug room inventory records are incomplete in that they fail to list: drug quantity at the start and end of each work day; amount of drug used; batch used in; and drug reconciliation with remarks if there are discrepancies,
- 4) Incoming drug pre-mix receiving records lack verification of a drug's general condition upon receipt and the initials of the person performing the checks,
- 5) Batch production records lack the following required information: mixing directions; batch size; and amount of flush material used. In addition, there is no record that the batch records are reviewed and initialed at the end of each workday,
- 6) Medicated feed bag tag labels are not proofread when copied from the master label. A copy of the proofed label is not maintained for at least a year after the batch has been used up,
- 7) Equipment flush materials were not stored in adequately identified or maintained containers to prevent possible mix-ups or sanitation problems,
- 8) Scales in the drug pre-mix storage room and in the production area have no records to verify their accuracy at least annually, and
- 9) Master production records are not initialed and dated after preparation or after changes or additions have been made.

Nelson & Sons Silver Cup Medicated / Abernathy 6/64 Pellets, batch #342090399, manufactured at your firm on 9-3-99, was labeled to contain Sulfadimethoxine at 2x x x. Your contracted testing laboratory's report of analysis reported sulfadimethoxine at 2 x x x, or only 50% of the declared potency.

Silver Cup Trout Pellets, batch #256051999, manufactured at your firm on 5-19-99, was labeled to contain 2 x x x sulfadimethoxine. Your contracted testing laboratory's report of analysis indicated sulfadimethoxine at 2 x x x, or only 50% of the declared potency.

You conducted no follow-up action to determine the cause of these sub-potent batches. These medicated feeds may be adulterated within the meaning of Section 501(c) of the Act, in that their strength differs, or quality falls below that which they purport to possess.

The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring 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 violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to seizure and injunction. Based on the results of the November 4 & 8, 1999 inspection, and review of your contracted test results (reports of analysis) for two sub-potent batches of medicated feeds produced by you, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds 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.

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Please notify this office in writing within 15 working days of the 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 the violations and prevent their recurrence. If corrective action cannot be completed within 30 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 response should be directed to Jeannette A Schmieg, Acting Compliance Officer, at the above address. If you have questions regarding this letter you may contact Ms. Schmieg at (303) 236-3026.

Sincerely,



Karen S. Kreuzer
Acting Director, Denver District

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