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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

January 23, 2002

WARNING LETTER

NWE-13-02W

VIA FEDEX

William Peracchio
(President/Central Connecticut COOP Farmer's Association)
200 Twin Hills Drive
Coventry, Connecticut 06238

Dear Mr. Peracchio:

An inspection of your medicated feed mill located in Manchester, Connecticut, conducted by Food and Drug Investigator Michael Sinkevich on December 11 and 12, 2001, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). Such deviations cause medicated 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). The deviations are as follows:

1. For feeds requiring an approved 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. If the medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. No assays were performed in the years 2000 and 2001 (21 CFR 225.58(b)(1)).
2. Adequate cleanout procedures for all equipment used in the manufacture and distribution of medicated feeds are essential to maintain proper drug potency and to avoid unsafe contamination of feeds with drugs. Your cleanout procedure fails to list

the Category II drugs histostat, rofenaid a [REDACTED]
[REDACTED] Further, you do not include the holding units in the clean out procedures.

3. Failure of your master record file to have adequate and approved formulations, manufacturing instructions and labeling. For example, your current master record file is dated October 22, 1979, and lacks adequate and approved formulations, manufacturing instructions and labeling.

The above is not intended to be 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.

Also noted during this investigation were rodent excreta pellets along the north wall of your manufacturing facility where the bagged raw ingredients are warehoused. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP 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 Medicated Feed Mill License under section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2). (This letter constitutes official notification under the law.) Based on the results of the December 11 and 12, 2001 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the 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.

You should notify this office, in writing, within fifteen (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 CGMP violations and prevent their recurrence. If corrective action cannot be completed within thirty (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.

Central Connecticut COOP Farmer's Association
Manchester, Connecticut 06040
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Your response should be directed to Bruce R. Ota, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello", with a long horizontal flourish extending to the right.

Gail T. Costello
District Director
New England District

cc: Charles White, General Manager
Central Connecticut COOP Farmer's Association
10 Apel Place
Manchester, Connecticut 06040