



February 20, 2004

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-4-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donald E. Orr, Jr.
President & General Manager
United Feeds, Inc.
4310 W. State Road
Sheridan, IN 46069

Dear Mr. Orr:

An investigation of your medicated feed mill located at 116 W. 2nd St., Gridley, IL, conducted by a Food and Drug Administration investigator on September 30 and October 2, 2003, found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). 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.

This was a joint inspection conducted by the Illinois Department of Agriculture and the Food and Drug Administration (FDA). This letter pertains only to the deviations found by the Food and Drug Administration investigator.

FDA's investigation found your firm had distributed a Type A, Category II drug to an unlicensed swine grower that resulted in subsequent animal deaths. Your firm failed to maintain daily drug inventory records for drugs used. For example:

Theoretical quantity of whole bags of drugs products recorded on the firm's "Main Drug Room Inventory" record is not always compared against an actual count of bags on hand. 21 CFR 225.42(b)(7).

- There is no record of such comparison for the theoretical balance of [redacted] bags of [redacted] on 1/28/03.
- There is no record of such comparison for the theoretical balance of [redacted] bags of [redacted] on 3/21/03.
- There is no record of such comparison for the theoretical balance of [redacted] bags of [redacted] on 9/5/03.

Theoretical quantity contained in partial bags of drug product as recorded on firm's "Drug Mixing Room Inventory" form is not always compared against an actual weight of remaining drug product. 21 CFR 225.42(b)(7).

- There is no record of such comparison for the theoretical balance of [REDACTED] lb. of [REDACTED] on 1/15/03.
- There is no record of such comparison for the theoretical balance of [REDACTED] lb. of [REDACTED] on 4/23/03.
- There is no record of such comparison for the theoretical balance of [REDACTED] lb. of [REDACTED] on 5/2/03.

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 products you manufacture and distribute are in compliance with the law.

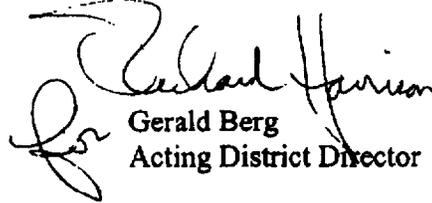
You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, 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 Federal Food, Drug, and Cosmetic Act and 21 CFR 515.22(c)(2). This letter constitutes official notice of CGMP violations. Based on the results of the 09/30 & 10/02/03 inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the method 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 drug 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 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 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.

Page 3

Your response should be directed to Matthew Sienko, Compliance Officer, at the above address. If you have any questions regarding this letter, you may call Mr. Sienko at (312) 353-5863, extension 4213.

Sincerely,

A handwritten signature in cursive script, appearing to read "Gerald Berg".

Gerald Berg
Acting District Director

cc: Steven Schneider, Operations Manager
United Feeds, Inc.
116 W. 2nd Street
Gridley, IL 61744