



August 2, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-40-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Swisher, Owner/CEO
United Feeds, Inc.
P.O. Box 108
Sheridan, IN 46069

Dear Mr. Swisher:

On February 20, 21 and 22, 2001, the Illinois Department of Agriculture (IDA) and the U.S. Food and Drug Administration made a joint inspection of your medicated feed facility, located at #1 United Lane, Griggsville, Illinois. The inspection revealed that this facility has sold and shipped a Category II Type A Medicated Article [(neomycin oxytetracycline (Neo-Terramycin)] to [REDACTED], which does not have a valid FDA Medicated Feed Mill License.

Removal of a Category II Type A Medicated Article from your facility is a violation of Section 512 (a)(1)(b) of the Federal Food, Drug and Cosmetic Act (the Act), and causes the new animal drug to be deemed unsafe for the purposes of Section 501(a)(5). The drug is unsafe, unless you have in your possession an unrevoked, written statement from the consignee, or notice from the Secretary (DHHS), to the effect that, with respect to the use of such drug in animal feed, such consignee holds a license and has in its possession current approved labeling for such drug in animal feed; or will, if the consignee is not a user of the drug, ship such drug only to a holder of a license.

Our joint inspection also found significant deviations from Current Good Manufacturing Practice (cGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations (21 CFR), Part 225]. Such deviations cause medicated feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Act. The medicated feeds are adulterated in that the methods used in, or the facilities or controls used for, manufacturing, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices. The significant deviations noted are as follows:

- Failure to perform a follow-up investigation of an out-of-limits assay, specifically for penicillin found to be super-potent [REDACTED]. A federal-contract inspection by the Illinois Department of Agriculture in February of 2000 also reported that no investigation was performed on two other drug assay failures, which occurred in October and December of 1999, for feed containing 3-Nitro-20 ([REDACTED]).

Our inspection of your Griggsville facility also disclosed a failure to clean scoops used to handle Medicated Articles, and a failure to prevent dust on drug component bags. Dust and/or feed ingredients were accumulated around bag-dump weigh hoppers in the mix area, and around the floor door and top chute of a dry/liquid feed mixer. The above-identified IDA inspection of February 2000 also noted a heavy accumulation of dust on floor, bulk containers and shelves in the component storage and mix areas, as well as contamination of contents of old drug containers with dust and other feed ingredients, as a result of poorly fitting lids.

The violations listed above are not intended to be all-inclusive. It is your responsibility as a medicated feed manufacturer to assure that all of your operations are in compliance with the law. This includes assuring that each site where your firm handles Category II Type A Medicated Articles adheres to the requirement not to ship to unlicensed or unauthorized parties. At the conclusion of the inspection, a Form FDA 483 (Inspectional Observations) was issued to and discussed with Mr. Jay Kiefer, Plant Manager, at the Griggsville facility. A copy of this form is enclosed for your information.

You should take prompt action to correct the above 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, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your FDA Medicated Feed 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 above inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, 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.

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 and products into compliance with the law. Your response should include each step that has been taken, or that will be taken, to correct the violations and prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay, and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: James T. Karpus, Compliance Officer, at the Chicago District Office.

Sincerely,

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Raymond V. Mlecko
District Director