

HFI-35

Public Health Service

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-19

December 21, 1998

Mr. Charles B. Syfrett, President
Syfrett Feed Company, Inc.
3079 N.W. 8th St.
Okeechobee, FL 34972

Dear Mr. Syfrett:

An inspection of your medicated feed mill located at Okeechobee, FL, conducted by Food and Drug Administration investigator Michelle Dunaway on August 11-13 and 17, 1998 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).

Our inspection found your mill failed to use any sequencing, flushing or manual clean out procedures between the manufacturing of medicated and non-medicated cattle feeds and you have no documentation to support the lack of such clean out procedures.

Our investigation also found at least five of the medicated cattle feeds manufactured by your mill contained unapproved drug combinations. These included: Brighton, Imagination and NFC Calf Feeds, which contained Lasolocid, Sulfamethazine and Chlortetracycline; Brighton Heifer feed, which contained Monensin, Sulfamethazine and Chlortetracycline and Syfrett Beef Feed which contained Lasolocid and Chlortetracycline. None of the above drug combinations are approved for cattle or any other species per 21 CFR 558.311, 558.140, 558.355 and 558.128. The use of the above drug combinations in the listed feeds causes the feeds to become adulterated within the meaning of Section 501(a)(6), because they are unsafe within the meaning of Section 512(a)(1)(A).

Our investigation further found that your firm had manufactured numerous batches of five poultry feeds containing a protein concentrate called "██████████" during the period April 15 through August 1, 1998, and the finished feeds failed to bear the required warning statement "Do not feed to cattle or other ruminants". The label for Pro-Pak does bear the required warning statement, since the ingredients include "Animal Protein Products", apparently from prohibited mammalian species.

Examples of your firm's finished poultry feeds containing ██████████ without the required warning statement: "Do not feed to cattle or other ruminants" include Gladstone Broiler Starter, Gladstone Broiler Finisher, Gladstone Withdrawal, Diamond Farms Starter and Diamond Farms Finisher. The lack of this warning statement causes these feeds to be misbranded within the meaning of Section 403(f) of the Act.

We note that since August 1, 1998 your firm is no longer using prohibited mammalian protein in the production of any of the above feeds.

We acknowledge receipt of your letter dated September 3, 1998, with copies of the revised formulas and labels for four of your cattle feeds attached. We note that the attached labels and formulas include three of the cattle feeds mentioned above, and document that the unapproved combinations have been removed from these feeds. If you have not already done so, you should examine all of your medicated feed formulas to ensure none of the remaining feeds contain unapproved drug combinations.

Review of your revised formula and label for "Syfrett Bishop Brothers Heifer and Dry Cow Feed-Medicated", "Syfrett Brighton Heifer Feed-Medicated", "Syfrett Brighton Calf Feed-Medicated", and "Syfrett Imagination Calf Feed-Medicated", found these products would not be acceptable for marketing. Type B or Type C medicated articles bearing the submitted labels would cause the feeds to be adulterated within the meaning of Section 501(a)(6).

SYFRETT BISHOP BROTHERS HEIFER & DRY COW FEED-MEDICATED

This product is unacceptable as follows:

- 1) Chlortetracycline is approved for use in feed for calves, beef and nonlactating dairy cattle at a rate of 10mg/lb of body weight per day; not 10 grams per ton. Furthermore, the level of the drug calculated from the submitted formula would be approximately 40 g/ton. The feed should contain approximately 400g/ton to provide 10mg/lb body weight/day.

The label description does not take into consideration the weight of the animals. Regardless, the rate displayed on the label would fall far below the necessary level needed to treat the condition indicated. The approved indications for use are for the treatment of **bacterial enteritis** caused by E. coli and **bacterial pneumonia** caused by *P. multocida* organisms susceptible to chlortetracycline. It is not approved for the indications listed on this label, i.e., foot rot and bacterial diarrhea.

- 2) If this is a Type C product, then feeding directions should be part of the label. If this is a Type B product, then mixing and feeding directions are required.
- 3) The use of chlortetracycline in cattle feed requires the following warning to be prominently displayed:

"A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."

SYFRETT BRIGHTON HEIFER FEED-MEDICATED

- 1) The feed label needs to define the feed as either a Type B or a Type C Medicated Feed. If this is a Type C product, then feeding directions should be part of the label. If this is a Type B product then mixing and feeding directions are required. Additionally, if this is a Type B product several additional warning statements are required including: "Feed Continuously" and "To be fed to heifers in confinement for slaughter" and; "Must be thoroughly mixed in feeds before use" and "Do not feed undiluted".
- 2) The caution statement for equines should read: "Do not allow horses or other equines access to formulations containing monensin. Ingestion of monensin by equines has been fatal." (The word "has" is underlined here only for emphasis and does not have to be underlined on the actual label.)

SYFRETT BRIGHTON CALF FEED-MEDICATED and SYFRETT IMAGINATION CALF FEED-MEDICATED

- 1) The labels must define the feed as either a Type B or a Type C Medicated Feed. If this is a Type C feed, then feeding directions should be part of the label. If this is a Type B feed then mixing and feeding directions are required.

- 2) The label lists the active ingredient Decoquinatate, but does not list the feeding rate of 22.7 mg per 100 lbs. of body weight per day.
- 3) The CFR reference for cattle and non-ruminating calves is for coccidiosis caused by *Eimeria bovis* and *E. zurnii* (not *E. zuernii*).
- 4) The formula for this feed contains a reference to the drug Lasalocid. Decoquinatate and Lasalocid is not an approved combination.
- 5) The label references the ingredient "Silicor". We are not aware of a feed ingredient called Silicor.

Additional Information

- 1) The "Official Publication" of the Association of American Feed Control Officials (AAFCO) may provide additional guidance and instructions. Copies may be obtained from Mr. Charles P. Frank, AAFCO Treasurer, Georgia Department of Agriculture, Plant Food, Feed and Grain Division, Atlanta, Georgia 30334.
- 2) There may be additional requirements for marketing feed products in an individual state. We recommend you contact Arthur B. Frassrand, Administrator, Feed Section, Florida Department of Agriculture and Consumer Services, 3125 Conner Blvd., ME-2, Tallahassee, Florida 32399-2650, telephone (850) 488-7626.
- 3) Regarding the use of Methoprene, a pesticide for fly control: You should be aware of the EPA requirements for usage, tissue residue limits and labeling for this or any other pesticide used in feeds.

The above comments are intended as guidance and should not be construed as complete or as approval of the labels.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. 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 the above violations and establish procedures to ensure the violations do not recur. Failure to promptly correct these deviations may result in regulatory and/or administrative sanctions being initiated by the Food and Drug Administration without further notice. These sanctions include, but are not limited to, seizure and/or injunction. Based on the results of

the August 11-13 and 17, 1998 inspection, 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.

Until the CGMP violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine will not approve a license application for your facility.

You should notify this office in writing within fifteen (15) days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen days, state the reason for the delay and the time within which corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please reply to Kendall W. Hester, Compliance Officer, Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4730.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, sweeping initial "D".

Douglas D. Tolen
Director, Florida District