



DEPARTMENT OF HEALTH AND HUMAN SERVICES

J 4246d
Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

August 27, 2003

VIA FEDERAL EXPRESS

Howard Brown, President
CR Brown Enterprises, Inc.
dba CR Brown Feeds
235 Milton Mashburn Boulevard
Andrews, NC 28901

Warning Letter
03-ATL-24

Dear Mr. Brown:

FDA conducted an investigation of your medicated feed mill located at 43 Rocky Creek Road, Andrews, North Carolina, on June 26 and July 1, 2003. Our investigator found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations, Part 225 (21 CFR 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 investigator also found deviations from labeling requirements that cause medicated feed you manufacture to be misbranded under section 502(a) of the Act and adulterated under sections 501(a)(6) and 501(c) of the Act.

Our investigation found the following deviations from CGMP requirements:

1. Failure to maintain a Master Record File and production records for the manufacture of a Type C medicated feed from a Category II, Type A medicated article [21 CFR 225.102(a)]. Specifically, you had no such records for the manufacture of medicated fish feeds top coated with a medicated premix containing sulfadimethoxine and ormetoprim [REDACTED]. Your firm has been manufacturing these medicated feeds since August 14, 2001.
2. Failure to perform periodic assays for drug components of the medicated feeds whose manufacture requires a medicated feed mill license [21 CFR 225.58(b)(1)]. Specifically, you did not perform any such assay for either of the two drug components in the medicated fish feeds referred to in item 1 above.

3. Failure to maintain a daily inventory record for each drug used in the manufacture of medicated feeds whose manufacture requires a medicated feed mill license [21 CFR 225.42(b)(6)].
4. Failure to establish and maintain adequate procedures for the receipt, storage and inventory control (receipt and use) of all drugs that are used in the manufacture and processing of medicated feeds [21 CFR 225.42(b)]. Similar to the deviation described in item 3 above, there were no inventory records generated for a Category I, Type A medicated article, i.e. medicated premix containing oxytetracycline (██████████), received, stored, and used in the manufacture of medicated feeds. With regard to storage, the two medicated articles in question were observed by our investigator in opened bags stored inside open containers, near automobile tires, next to a wall with loose insulation and a large uncovered opening to the exterior of the building.
5. Failure to ensure that the equipment used to manufacture medicated feeds possesses the capability to produce a medicated feed of intended potency, and purity [21 CFR 225.30(b)(1)]. Specifically, you could not provide any supporting evidence showing that the concrete cement mixer used by your firm to manufacture medicated feeds is adequate for its intended function. In addition, you could not provide any record or other evidence showing that the scale used to weigh the medicated articles has been calibrated or otherwise tested for accuracy upon installation and at least once a year thereafter.
6. Failure to establish adequate cleanout procedures for all equipment that comes in contact with the active drug component, feeds in process, or finished medicated feeds [21 CFR 225.65(b)]. For example, the cleanout procedure described to our investigator, which consisted of banging the side of the concrete cement mixer with a rubber mallet to knock loose any residuals remaining from the previous feed batch does not appear adequate as evidenced by old residue build-up visible on all interior surfaces of the mixer. Since more that one type of medicated feed is manufactured using the same mixer, poor or ineffective cleanout procedures are likely to result in contamination of feeds with drugs. In addition, both the plastic scoop and container used by the mill manager to weigh the medicated articles used in the manufacture of medicated feeds, showed excessive residue build-up. These two pieces of equipment also come in contact with two different medicated articles containing different drug components, which can result in unsafe contamination with drugs.
7. Failure to maintain production and distribution records identifying the formulation, date of mixing, and date of shipment of medicated feeds [21 CFR 225.102, 225.110]. Specifically, you had no such records for the manufacture of medicated fish feeds top-coated with a medicated premix containing oxytetracycline (██████████).

In addition to the above violations, we have serious concerns over the formulation and labeling discrepancies we observed. Your labeling procedure of attaching a label card from a discontinued similar type medicated feed to your current medicated feed products misbrands the products within the meaning of section 502(a) of the Act. The labeling is false or misleading because the percentages of active ingredients declared on "Brown's Medicated Trout Grower" and the feeding instructions on the "Brown's Trout Grower" are incorrect. The use of these old

label cards also renders your medicated feed adulterated within the meaning of section 501(c) of the Act in that the drug strength of the medicated feed differs from the label declaration. The medicated feed is also adulterated under section 501(a)(6) of the Act. A medicated feed is "unsafe" under section 512(a)(2)(C) of the Act if its labeling or use do not conform with the drug's published approval. If followed, the "Feeding Directions" for the oxytetracycline medicated feed results in a total drug intake that exceeds the permitted level of 2.5 to 3.75 grams per pound of fish, 21 CFR 558.450(d)(2). As a result, this medicated feed is "unsafe" under section 512(a)(2)(C) of the Act and therefore adulterated under section 501(a)(6).

The above is not intended as an all-inclusive list of violations of the Act. As a manufacturer of medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

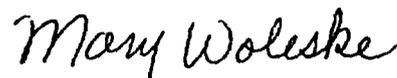
You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, 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).

On June 26, 2003, you provided our investigator with a written request, via Form FDA 2438b, to withdraw your Medicated Feed Mill License # [REDACTED] and cancel your firm's registration with the Food and Drug Administration. This request has been forwarded to our Center for Veterinary Medicine and a copy is enclosed for your reference.

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 violations and prevent their recurrence. If corrective action cannot be completed within 15 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 reply should be sent to the attention of Carlos A. Bonnin, Compliance Officer, at the address noted in the letterhead.

Sincerely,



Mary H. Woleske, Director
Atlanta District

Enclosure