



July 11, 2002

WARNING LETTER NO. 2002-NOL-37

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Betty L. Mitchell, President
B.L. Mitchell, Inc.
103 Highway 82
Leland, Mississippi 38756

Dear Mrs. Mitchell:

An inspection of your aquaculture drug repacking operation, located at 103 Highway 82, Leland, Mississippi, conducted by a U.S. Food and Drug Administration (FDA) investigator during April 30 - May 2, 2002, found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for pharmaceuticals, Title 21, *Code of Federal Regulations*, Part 210 (21 CFR 210) and Part 211 (21 CFR 211). Such deviations cause the aquaculture drugs repacked at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the methods used in, or the facilities or controls used for, processing, packing or holding of such drugs do not assure that such drug products meet the requirements of the Act. The deviations were presented to you on Form FDA 483, Inspectional Observations, at the close of the inspection on May 2, 2002.

The significant observations were as follows:

- You failed to test incoming bulk iodine disinfectant, nitrofurazone, and container closures to meet product specifications;
- You failed to have a written testing program to assess the stability characteristics of your nitrofurazone products (to support the expiration date listed on the label);
- You did not maintain master packaging and labeling control records;
- You have not established written procedures for packaging and labeling control;
- You released all of your finished products without review and approval by a quality control unit;
- You have failed to establish or follow written procedures for the inventory and warehousing of bulk drugs and packaging components; and,

- You have failed to establish written procedures for cleaning and maintenance of equipment, including utensils.

In addition to being adulterated, as set out above, your nitrofurazone product is misbranded with the meaning of Section 502(f)(1) of the Act in that the labeling does not have the required caution statement: "HUMAN WARNING: Carcinogenesis: Nitrofurazone, the acting ingredients has been shown to produce mammary tumors in rats and ovarian tumors in mice. Additionally, some people may be hypersensitive to this product. Either wear gloves when applying, or wash hands afterwards."

Further, your *AURUDYNE IODINE DISINFECTANT* is misbranded under Section 502(a) of the Act, as described under 21 CFR 201.17, in that the label does not bear an expiration date. Absent appropriate stability data showing that this product is stable for at least three years, *AURUDYNE IODINE DISINFECTANT* is not exempt from the requirement to bear an expiration date as described by 21 CFR 211.137(h). Based on information obtained during the inspection noted above, your firm does not have such data. Failure to bear an expiration date is also a CGMP violation which makes the product adulterated under Section 501(a)(2)(B) of the Act, as set out above.

The above is not intended to be an all-inclusive list of deviations from the Act and the regulations. As a repacker of aquaculture drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the awarding of contracts. Failure to promptly correct these deviations may result in regulatory action, such as seizure and/or injunction, without further notice.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. 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 fifteen (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.

Please send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504)253-4519.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: FDA Form 483