



October 10, 2002

**WARNING LETTER NO. 2003-NOL-01**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Alton J. Hall, D.V.M., President  
Natchez Animal Supply Company  
201 John R. Junkin Drive  
Natchez, Mississippi 39120

Dear Dr. Hall:

On August 27, 28, September 3 and 5, 2002, U.S. Food and Drug Administration investigators inspected your facility located at 201 John R. Junkin Drive, Natchez, Mississippi. During the inspection, our investigators documented significant deviations from Current Good Manufacturing Practice regulations (CGMP) Title 21, *Code of Federal Regulations*, Part 211, in conjunction with your firm's aquaculture drug repackaging operations. Such deviations cause your aquaculture drug, Formalin-F, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations observed regarding your firm's repackaging of the drug product, Formalin-F (formaldehyde), are as follows:

- Testing and release of the drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release [21 CFR 211.165(a)];
- The identity of formaldehyde is not verified by conducting at least one U.S.P. identity test [21 CFR 211.84(d)(1)];
- Actual yield and percentages of theoretical yield are not determined at the depletion of the bulk drug product [21 CFR 211.103];
- Stability data are not available for the finished drug product [21 CFR 211.166(b)];
- Batch production and control records do not determine nor document the actual drug product fill weights during the course of processing each batch of drug product produced [21 CFR 211.188(b)(4)];

- Component, drug product containers and closures, and labeling records do not include the results of tests or examinations performed [21 CFR 211.184(b)];
- Master production and control records are not maintained [21 CFR 211.186];
- Bulk drug product is not tested after storage in conditions that might adversely effect the component [21 CFR 211.87];
- Distribution records do not contain the lot number of the drug product [21 CFR 211.196];
- Repackaging equipment is not cleaned nor sanitized between batches [21 CFR 211.67(a)];
- Records are not kept for the maintenance, cleaning, sanitizing, and inspection of repackaging equipment [21 CFR 211.67(c)];
- Records of major equipment cleaning, maintenance, and use are not included in individual equipment logs [21 CFR 211.182];
- Employees involved with repackaging the drug product have no documented CGMP training [21 CFR 211.25(a)]; and,
- Written complaint procedures are not established, nor is a complaint file maintained [21 CFR 211.198].

The deviations regarding your firm's lack of written standard operating procedures are as follows:

- A written testing program designed to assess the stability characteristics of drug products is not established [21 CFR 211.166(a)];
- Written procedures are not established for production and process controls designed to assure drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100(a)];
- Sampling and testing plans for drug products are not described in written procedures which include the method of sampling and number of units per batch to be tested [21 CFR 211.165(c)];
- Responsibilities and procedures applicable to the quality control unit are not in writing [21 CFR 211.22(d)];
- Written procedures for the preparation of master production and control records are not prepared [21 CFR 211.186(a)];

- Written procedures are not established to describe, in sufficient detail, the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures [21 CFR 211.80(a)];
- Written procedures are not established for the cleaning and maintenance of equipment used in the manufacture, processing, packing, or holding of a drug product [21 CFR 211.67(b)];
- Written procedures are not established for the use of suitable cleaning and sanitizing agents designed to prevent the contamination of equipment, drug product containers, closures and packaging, or labeling materials [21 CFR 211.56(c)];
- Written procedures are not established for the warehousing of drug products [21 CFR 211.142];
- Written procedures are not established for the holding of returned drug product [21 CFR 211.204];
- Written procedures are not established to describe, in sufficient detail, the receipt, identification, storage, handling, sampling, and examination of labeling and packaging materials [21 CFR 211.122(a)];
- Written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products are not established [21 CFR 211.130];
- Written procedures are not established to describe, in sufficient detail, the control procedures employed for the issuance of labeling [21 CFR 211.125(f)];
- A system is not established by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary [21 CFR 211.150(b)];
- Written procedures are not established for at least annual evaluations to review records associated with a representative number of batches, whether approved or rejected [21 CFR 211.180(e)(1)];
- Written distribution procedures are not established [21 CFR 211.150]; and,
- Written procedures are not established to describe the handling of all written and oral complaints regarding the drug product [21 CFR 211.198(a)].

The above identification of violations is not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the CGMP regulations.

The veterinary drug product manufactured by your firm also is misbranded under Section 502(o) of the Act in that it was manufactured in an establishment that was not registered under Section 510 of the Act and your veterinary drug product has not been listed as required by Section 510(j) of the Act. Should you continue your veterinary drug manufacturing operations, you must

register your firm as a Drug Establishment, list your veterinary drug products, and fully comply with the CGMP regulations. We are enclosing forms for you to register your establishment and list your products.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating. We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within fifteen (15) days from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

Enclosures: Drug registration and listing forms  
Form FDA 483