



DEPARTMENT OF HEALTH & HUMAN SERVICES

August 31, 2000

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER
SJN-00-21

CERTIFIED MAIL
Return Receipt Requested

Mr. James Linsey
CEO
Consolidated Nutrition, L.C.
P.O. Box 2048
Omaha, NE 69154

Dear Mr. Linsey:

During a July 31 to August 2, 2000 inspection of your medicated feed manufacturing plant, Master Mix of Puerto Rico, Inc., located at Road 461, La Militar St., Hatillo, P.R. 00751, our Investigators Carlos Medina and Arlene Badillo documented on an FDA-483, Inspectional Observations form, several deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 225). These deviations are in connection to your firm's manufacturing of Master Mix and Red Hat brand medicated feed products, causing these to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. You failed to conduct periodic potency assays for drug components on representative samples of each medicated feed made from drug pre-mixes to ensure they conform to specified requirements of identity, strength, quality, and safety. {21 CFR 225.158}.
2. Failure to calibrate your production weighing scales in accordance with your established calibration and maintenance program to ensure they maintain their accuracy for their intended use. {21 CFR 225.130}. You require biannual calibration services, yet on July 31, 2000, our investigators found four of the scales in use with a May 2000 re-calibration date that expired.

3. Failure to maintain your manufacturing and storage facility in sanitary conditions in that live and dead rodents, and rodent excreta pellets were observed at six (6) separate locations of the plant, {21 CFR 225.120}. Excreta pellets were observed on bags of raw material.

We acknowledge receipt of letter dated August 14, 2000 from Mr. Randy Sample, Director of Regulatory Compliance, responding to the FDA-483. Our review indicates your responses are not adequate for FDA-483 Observations 1, & 3 as mentioned in items 1 and 2 above. Note that establishments that do not require a Feed Mill License per 21 CFR 225.1(b)(2) must comply with 21 CFR 225.120 to 225.202, therefore, although not at the rate specified in 21 CFR 225.58(b), 21 CFR 225.158 does enforce the requirement for periodic assay of Type B & C, Category I medicated feed. Likewise, 21 CFR 225.130 requires scales and metering devices be accurate, so this requires the need to check them and at a frequency deemed necessary for their intended use. Also, the response to FDA-483 Observation 4, although it mentions corrective efforts, it does not detail how and when you will implement corrections, nor what added assurance your housekeeping and sanitation program will include to control the ingress of vermin and prevent contamination of raw material and finished product.

Concerning FDA-483 Observation 2, we understand that the policy the Center for Veterinary Medicine established, and continues to accept, permits mixer blend uniformity studies for medicated feed using low inclusion ingredients other than the drugs. However, we advise you that such studies need to be scientifically sound and based on current state-of-the-art validation principles to be valid. Therefore, it is your responsibility to assure that feed mixer (blend uniformity) studies hold up to the scrutiny of today's requirements. At the least, we expect that there be established processing parameters, written pre-determined specification and acceptance criteria for the study, and that the data generated be analyzed against those specifications and criteria with statistically valid conclusions. From the information provided to the investigators, we can not conclude your study substantiates and assures that feed blend uniformity is consistently achieved.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the

Mr Limsey
August 31, 2000
Page 3

Good Manufacturing Practice Regulations. A copy of 21 CFR Part 225 is attached for your reference.

You should take prompt action to correct these cGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these cGMP 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 Title 21, Code of Federal Regulations, Part 514.115(c)(2). This letter constitutes official notification under the law, and provides you an opportunity to correct the above deficiencies.

Please notify the San Juan District office in writing, within 15 working 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 these or similar violations.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Andres Toro, Compliance Officer.

Sincerely,

Wayne Matthews for
Mildred R. Barber
District Director

Cc:

Angel E. Cardona
General Manager
Master Mix of P.R., Inc
P.O. Box 908
Hatillo, P.R., 00659-0908

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