



DEPARTMENT OF HEALTH & HUMAN SERVICES

m424Cn

September 29, 2000

Food and Drug Administration

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

WARNING LETTER  
SJN-00-25

CERTIFIED MAIL  
Return Receipt Requested

Mr. Paulino De Jesus  
President  
Empresas Avicolas Colsus, Inc.  
P.O. Box 447  
Arroyo, P.R. 00615

Dear Mr. De Jesus:

During the August 17 & 25 2000 inspection of your medicated feed manufacturing plant, located at Rd 753 Km 5.6, Bo Yaurel, Arroyo, Puerto Rico, 00714, Investigator Carmelo Rosa, reported 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 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 establish and follow adequate production procedures to avoid unsafe contamination of medicated and non-medicated feeds. {21 CFR 225.165}. Silos are indiscriminately used to store medicated and non-medicated feeds without cleanout control procedures, and there are no adequate operating procedures, such as flushing, used for common equipment like the feed mixers to avoid cross-contamination between the different feeds manufactured.
2. You failed to conduct periodic potency assays for the drug components on representative samples of each medicated feed made from drug articles and drug pre-mixes to ensure they conform to specified requirements of identity, strength, quality, and safety. {21 CFR 225.158}.

3. Failure to conduct and maintain documented studies that show that your manufacturing equipment is capable of producing medicated feed of intended potency, purity, and safety. {21 CFR 225.130}. You have no data to demonstrate that the mixer/blender can consistently achieved a uniform, not even test studies using low inclusion ingredients other than the drugs, and there is no formal program in place for such studies.
4. There are no established inventory record controls for the receipt and use of all Type A medicated article and Type B medicated feeds used in the manufacturing of your medicated feeds as required in 21 CFR 225.142.
5. You failed to maintain records to identify the formulation and date of mixing for each and every production of medicated feeds in accordance with 21 CFR 225.202.
6. Failure to calibrate your production weighing scales in accordance with an established calibration and maintenance program to ensure they maintain their accuracy for their intended use. {21 CFR 225.130}. You have not calibrated any of your scales since 1993 and 1994, yet you continue to use them to measure pre-mixes and drug articles.
7. Failure to maintain your manufacturing equipment in a reasonably clean and orderly manner to assure the strength, purity, and safety of medicated feed you manufacture in accordance with 21 CFR 225.130.

The above are serious deviations that show a gross disregard for the Current Good Manufacturing Practice Regulations (cGMP) for medicated feed, and which include recurrent deficiencies reported to you during our inspection of September 1999. We further advice you that the practices described in item 1 above concerning the potential of cross-contamination may cause non-medicated feed to be adulterated within the meaning of Section 402(a)(2)(D) of the Act.

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

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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,



Mildred R. Barber  
District Director