

HFI-35



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

M844N

Telephone: [718] 340-7000 [Ext 5301]

WARNING LETTER

Certified Mail Return Receipt Requested

Mr. Lloyd Corwin
President
Eastport Feeds, Inc.
140 East Moriches Blvd,
Eastport, New York 11941

April 21, 1997

Ref: 49-NYK-97

Dear Mr. Corwin:

An inspection of your medicated feed mill located at Eastport, New York, conducted by a Food and Drug Administration investigator between the dates of March 28 and April 11, 1997, found significant deviations from Current Good Manufacturing Practice (CGMP) for Medicated Feeds regulations (Title 21, Code of Federal Regulations, Part 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) as follows:

Failure to conduct and record an investigation and implement corrective action into findings of medicated feed assay results not within assay limits as follows; ormetoprim assay for Duck Developer, batch # 3264; ormetoprim assay for Turkey Starter, batches # 3166, # 3157 and #3648; ethopabate assay for Pullet Grower, batch #3315.

Also, your firm has failed to report these failures to meet specifications to FDA's Center for Veterinary Medicine as required by 21 CFR 510.301.

The above identification of violations and the observations on the FDA-483 issued at the end of the inspection are not intended to be an all-inclusive list of deficiencies at your facility. You are responsible for assuring that your overall operation and 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 Applications under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). This letter constitutes official notification under the law. Based on the result of this inspection, evaluated together with the evidence before FDA when the Medicated Feed

Eastport Feeds, Inc.

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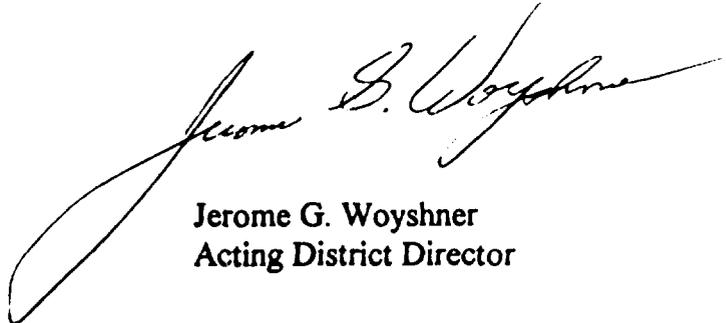
Applications were approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

Until the CGMP violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 850 Third Avenue, Brooklyn, NY 11232, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,



Jerome G. Woyshner
Acting District Director