



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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March 04, 2003

WARNING LETTER
CIN-03-16534

Featx

William E. Leininger,
Director of Operations
Buckeye Egg Farm L.P.
11212 Croton Road
Croton, OH 43013

Dear Mr. Leininger:

An inspection of your medicated feed mill located at 10750 Croton Road, Croton, OH 43013, conducted by Food and Drug Administration investigators, on 1/27,30/2003, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 CODE OF FEDERAL REGULATIONS, Part 225). Such deviations cause 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.

Our investigation found:

- 1) failure to conduct potency assays on at least three representative samples of each feed required to be manufactured by a licensed feed mill at periodic intervals during the calendar year [21 CFR 225.58(b)(1);
- 2) failure to maintain a daily inventory record for each drug used [21 CFR 225.42(b)(7)];
- 3) failure to calibrate scales and metering devices at least once a year to insure their accuracy [21 CFR 225.30(b)(4)];
- 4) failure to properly identify drugs in the mixing area to maintain their integrity and identity [21 CFR 225.42(b)(4);
- 5) failure to use all Type B medicated feed articles in accordance with labeled mixing directions [21 CFR 225.142];
- 6) failure to have a qualified person check, date, and sign or initial each Master Record File [21 CFR 225.102(b)(1);
- 7) failure to identify medicated feed with appropriate labeling which, if adhered to, will assure the article is safe and effective for its intended purpose [21 CFR 225.80(a)].

In addition to the deviations described above, our investigators found that your products, which contain or may contain prohibited materials, fail to bear the caution statement: "Do not feed to cattle or other ruminants", as required by 21 CFR 589.2000(d). This causes your medicated feed to be misbranded within the meaning of section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act.

Your firm has also failed to maintain a current Drug Establishment Registration in that your registration expired in April 2001. This causes your medicated feed to be misbranded within the meaning of section 502(o) of the Federal Food, Drug, and Cosmetic Act.

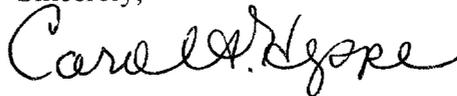
The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

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 21 CFR 515.22(c)(2). This letter constitutes official notice under the law of CGMP violations. Based on the results of the 01/27,30/2003 inspection, 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.

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 CGMP violations and prevent their recurrence. If corrective action cannot be completed within 30 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.

Your response should be directed to Charles S. Price Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097. If you have any questions regarding this letter, you may call Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,



Carol A. Heppe,
District Director
Cincinnati District

Cc: Stephen J. Schell,
Feed Mill Manager
Buckeye Egg Farm
10750 Croton Road
Croton, OH 43013