



DEPARTMENT OF HEALTH & HUMAN SERVICES

93920d
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

March 24, 2003

WARNING LETTER NYK 2003-16

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Phillip M. Dickson, President
Leo Dickson & Sons, Inc.
5229 Bonny Hill Road
Bath, New York 14810

Dear Mr. Dickson:

An investigation performed by U.S. Food and Drug Administration Investigators Steven J. Libal and Andrew M. Abramowitz included an inspection of your dairy farm on January 13, 16 and 28, 2003. The investigation confirmed you offered two cows for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, your extra label usage, and the illegal tissue residues that resulted, caused the drug products [REDACTED] and [REDACTED] to become adulterated within the meaning of Section 501(a)(5) of the Act.

On July 12, 2002 a dairy cow bearing farm tag 294 was treated for pneumonia at your farm. Treatment included administration of a 15cc intramuscular injection of [REDACTED]. The cow was subsequently offered for sale for human food on July 18, 2002 through trucker [REDACTED] and cattle dealer [REDACTED]. USDA analysis of samples collected from that animal on July 19, 2002 at [REDACTED] identified the presence of 2.47 parts per million (ppm) flunixin in liver tissue.

A tolerance of 0.125 ppm has been established for residues of flunixin in cattle liver (Title 21 Code of Federal Regulations 556.286). However, as stated on the drug label [REDACTED] is not approved for use in lactating or dry dairy cattle. The presence of flunixin at the reported level in edible tissue from a lactating or dry dairy cow causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about May 6, 2002 you sold a cow identified with farm tag 623 for slaughter for human food. Prior to sale that cow was treated for pneumonia at your farm. Treatment included the administration of two 20cc intramuscular injections per day of [REDACTED] for a three day period. The

dosage administered is at least double the highest daily dosage (3000 units per pound of body weight) recommended on the product label, and exceeds the 1.0 ml recommended dosage limit per injection site. The cow was trucked from your farm by [REDACTED] and was sold through cattle dealer [REDACTED]

USDA analysis of samples collected from that cow on May 7, 2002 at [REDACTED], identified the presence of 0.65 parts per million (ppm) penicillin in kidney tissue. A tolerance of 0.05 parts per million has been established for residues of penicillin in the uncooked edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). The presence of penicillin at the reported level in the kidney of this cow causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found you hold animals under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, you are adulterating the veterinary drugs [REDACTED] and [REDACTED] within the meaning of Section 501(a)(5) of the Act. These drugs become adulterated when you fail to use them either in accordance with their labeled instructions, or in compliance with extralabel use regulations. Use of these drugs contrary to their labeled instructions, resulting in residues which may present a risk to public health and which are above an established tolerance causes the drugs to be unsafe within the meaning of section 512 of the Act.

USDA analysis of tissue samples collected from four additional cows which were housed and treated at your farm prior to sale, also revealed illegal drug residues. Two of the cows were identified as having been offered for sale by an employee of your farm, [REDACTED] and two were identified as having been offered for sale by dairy farmer [REDACTED] whose cows were being maintained on your farm. Samples from the [REDACTED] cows revealed a gentamicin residue of 06.52 ppm in kidney tissue from a cow bearing farm tag 662 slaughtered at [REDACTED] on 10/11/02, and another gentamicin residue of 04.49 ppm in kidney tissue from a cow bearing back tag 21NP5510 slaughtered at [REDACTED] on 10/18/02. Samples from the [REDACTED] cows revealed a gentamicin residue of 03.46 ppm in kidney tissue from a cow slaughtered on 8/30/02 at [REDACTED] and a gentamicin residue of 03.77 ppm in kidney tissue from a cow slaughtered 8/23/02 at [REDACTED]. There is no permitted level for residues of gentamicin in edible tissues of cattle.

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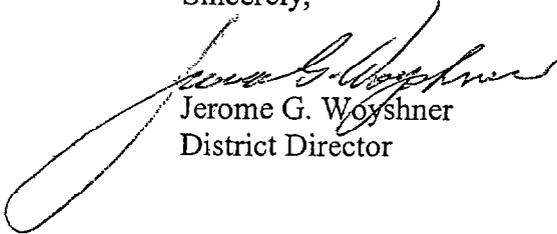
This letter is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,


Jerome G. Woyshner
District Director

cc: Loren L. Dickson, Treasurer
Leo Dickson & Sons, Inc.
5229 bonny Hill Road
Bath, New York 14810

Leland J. Dickson, Secretary
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[REDACTED]