



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

January 17, 2002

WARNING LETTER NYK 2002-20

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bennett J. Palmer, Jr., Co-Owner
Palmer Farms
10089 Warner Gulf Road
Holland, NY 14080

Dear Mr. Palmer:

An investigation performed by U.S. Food and Drug Administration Investigator Linda M. Pyjas included an inspection of your dairy farm on November 15 and 20 and December 13 and 17, 2001. That inspection, and the related investigation, confirmed that in December 2000, and again in May 2001, you offered animals for sale for human consumption which were found to contain illegal drug residues.

On or about December 19, 2000, you sold six cows for slaughter, including one assigned barn tag number 807 which had been treated with [REDACTED] brand PEN-AQUEOUS (Penicillin G Procaine) at your farm. That cow was subsequently assigned back tag 2473, and was slaughtered on December 19, 2000 at [REDACTED], NY. USDA analysis of tissue samples collected from that cow identified the presence of 0.55 ppm penicillin in the kidney.

On or about May 30, 2001 you sold a cow assigned barn tag number 621 to Ford Brothers Wholesale Meats. That cow had also been treated with [REDACTED] PEN-AQUEOUS at your farm. That cow was subsequently assigned back tag number 3757 and was slaughtered May 30, 2001 at [REDACTED], NY. USDA analysis of tissue samples collected from that cow identified 0.06 ppm penicillin in both the kidney and liver

A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). The presence of this drug, at the reported levels, in edible tissues of these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

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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 animals have been treated only with drugs which have been approved for use in those species, 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.

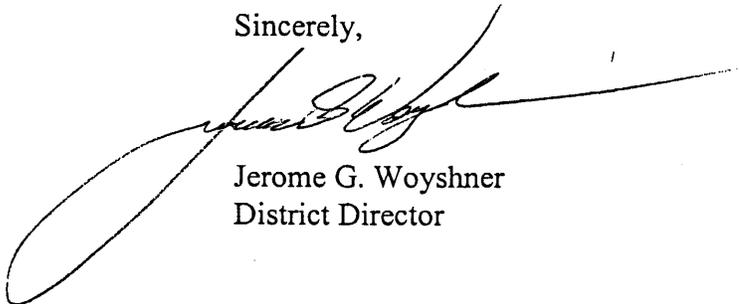
In addition, use of the veterinary drug product AGRIPHARM PEN-AQUEOUS contrary to its approved labeling causes that drug product to be adulterated within the meaning of Section 501(a)(5) of the Act. Use of this drug without following the specified withdrawal periods causes it to be unsafe for use.

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,

A handwritten signature in black ink, appearing to read 'Jerome G. Woysner', is written over a large, stylized loop that extends to the left and then curves back up and to the right.

Jerome G. Woysner
District Director

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cc: Gregory L. Palmer, Co-Owner
Palmer Farms
10089 Warner Gulf Road
Holland, NY 14080

cc: [REDACTED]
[REDACTED]
[REDACTED]

cc: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]