



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MSI 360n

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

February ⁶/₂, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-24

Donald E. Taber, Owner
Donley Farms Inc.
312 East 20 North
Shoshone, Idaho 83352-5300

WARNING LETTER

Dear Mr. Taber:

An investigation at your dairy located at 312 East 20 North, Shoshone, Idaho by our investigator on November 29 through December 1, 2000, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On or about June 28, 2000, you sold a culled dairy cow identified on USDA sample # 407257 collected on June 28, 2000 for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the kidney at 64.80 parts per million (ppm). There is no allowable tolerance for gentamicin in the edible tissue of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions... whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

Donald E. Taber, Owner
Donley Farms Inc., Shoshone, Idaho
Re: Warning Letter SEA 01-24
Page 2

For example, our investigator noted the following conditions on your farm:

1. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
2. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

We request that you take prompt action to ensure that dairy cows and calves which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Our investigation revealed that the gentamicin residue came from use of Gentamicin Sulfate Veterinary on your dairy herd. Gentamicin is not approved for use on dairy cows without a written prescription. Although you had a prescription for gentamicin, it was not for the treated cow and can be considered off label use which is a deviation from Title 21, Code of Federal Regulations (21 CFR), Part 530. We also note that the withdrawal time stated on the prescription label was 10 days for milk and 30 days for meat. From our experience with another gentamicin cases the withdrawal time for gentamicin in meat is up to 18 months, not 30 days.

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. Extra label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in Part 530.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Donald E. Taber, Owner
Donley Farms Inc., Shoshone, Idaho
Re: Warning Letter SEA 01-24
Page 3

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Bruce Williamson, Compliance Officer, (425) 483-4976.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written over a horizontal line.

Charles M. Breen
District Director

Enclosure:
Form FDA 483

CC:
Dr. Ahmed/USDA/FSIS/Tissue Residue
Landmark Center, Suite 300
1299 Farnam St.
Omaha, Nebraska 68102