



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M41540

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Reference: 2918675

August 29, 2000

Jack Prince, President
Dairymen's Division, Land O'Lakes Dairy Foods
400 South M Street
Tulare, California 93274-5431

WARNING LETTER

Dear Mr. Prince:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility on April 17 and 19, 2000. During the inspection, Randy L. Elsberry, Pacific Regional Milk Specialist, collected records documenting that cheese, whey protein concentrate powder, whey butter and buttermilk powder had been manufactured from [REDACTED] gallons raw milk that contained antibiotic residues of Penicillin G.

Our investigation revealed that your firm used the raw milk received from [REDACTED] on March 21, 2000 to manufacture the above products. California Department of Food and Agriculture analyses of that milk revealed that it contained 6.8 ppb Penicillin G, in excess of the zero tolerance for penicillin in milk and all products made from milk as specified in Title 21 of the Code of Federal Regulations Section 556.510(b) [21 CFR Section 556.510(b)]. FDA has reviewed the analytical data and found it to be scientifically sound.

The raw milk and products made from the milk are therefore adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Federal Food Drug and Cosmetic Act (the FD&C Act) in that they bear or contain the new animal drug, Penicillin G, that is unsafe within the meaning of Section 512 of the FD&C Act.

It is your responsibility to assure that your raw materials are in compliance with the law before they are processed. You should take prompt action to correct the violations such that they do not recur. Failure to promptly correct the violations may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert B. Johnson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Robert B. Johnson
Acting District Director
San Francisco District