



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

November 26, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 08

Daniel E. Zagzebski, President of Administration
Randall J. Lewis, President of Operations
Co-Owners
Lemke Cheese and Packaging Co., Inc.
101 Devoe Street, P.O. Box 688
Wausau, Wisconsin 54402

Dear Messrs. Zagzebski and Lewis:

On July 7 and 8, 2003, investigators with the Food and Drug Administration conducted an inspection of your facility located at 101 Devoe Street, Wausau, Wisconsin. During this inspection, the investigator collected a sample of "FANCY SHREDDED COLBY CHEESE & BRICK CHEESE BLEND," coded "8KCC 03 188 14." Our investigator observed that this product was produced by shredding and blending Cheddar Cheese and Monterey Jack Cheese.

The Cheddar and Monterey Jack Cheese blend is misbranded within the meaning of section 403(b) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 343(b)] because it is offered for sale under the name of another food, namely Colby Cheese & Brick Cheese Blend. The product is further misbranded under section 403(g) of the Act [21 U.S.C. 343(g)] because the label represents the product as a blend of Brick Cheese and Colby Cheese, which are subject to the standards of identity established under Title 21, Code of Federal Regulations (21 CFR), sections 133.108 and 133.118, respectively.

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Daniel E. Zagzebski and Randall J. Lewis
November 26, 2003

Failure to make prompt corrections may result in further enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunction against the manufacturer of illegal products.

This letter does not represent a comprehensive review of all of the products manufactured by your firm, nor does it represent a complete review of all product labeling. As owners, it is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated in the letterhead. Ms. Wisecup may be reached at (612) 758-7114.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TSW/ccl



xc:

