



Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone 612-334-4100

November 1, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 04

Gerhard H. Simon
President
Lactoprot USA
2819 Highway F South
Blue Mounds, Wisconsin 53517

Dear Mr. Simon:

An inspection of your facility was conducted on June 27, July 1, and July 3, 2002. This inspection was conducted to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and implementing regulations contained in Title 21, Code of Federal Regulations, Part 133 (21 CFR 133).

During this inspection our investigator obtained documentation regarding the production of several of your products. A review of these records and observations made by the investigators show your products to be misbranded within the meaning of Section 403 of the Act. The specifics of each deviation and the applicable sections of the Act and regulations follow:

Pasteurized process cheese is subject to the standard of identity found in 21 CFR 133.169. The optional dairy ingredients that may be used in pasteurized process cheese are specified in § 133.169(d)(2) as "[c]ream, anhydrous milkfat, dehydrated cream, or any combination of two or more of these, in such quantity that the weight of the fat derived therefrom is less than 5 percent of the weight of the pasteurized process cheese." Milk protein concentrate is not listed in § 133.169(d)(2) as an optional dairy ingredient that may be used in pasteurized process cheese. However, according to your Work Order for *Wauzeka* brand *Wauzeka* Smoked Pasteurized Process Cheddar & Swiss Cheese, 4 ounce pack, this product includes Milk Protein Concentrate (MPC).

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Pasteurized process cheese food containing fruits, vegetables, or meats is subject to the standard of identity found in 21 CFR 133.174. According to § 133.174(a), pasteurized process cheese food containing fruits, vegetables, or meats is further subject to the requirements of § 133.173, with specified exceptions. The optional dairy ingredients permitted in § 133.173(d) are "...cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, albumin from cheese whey, and skim milk cheese for manufacturing." Milk Protein Concentrate is not listed as an optional dairy ingredient in § 133.173(d) and is not listed as an exception in § 133.174(a). However, according to the Work Order for your Lactoprot brand Roasted Garlic Gourmet Flavored Cheese Pasteurized Process Cheese Food with Roasted Garlic, 6-ounce package, this product includes Milk Protein Concentrate. According to information obtained during the inspection, the physically sampled Roasted Red Bell Pepper Pasteurized Process Cheese Food and Garlic Pasteurized Process Cheese Food also contain MPC.

Pasteurized process cheese spread with fruits, vegetables, or meats is subject to the standard of identity found in 21 CFR 133.180. According to § 133.180(a), pasteurized process cheese spread with fruits, vegetables, or meats is further subject to the requirements of § 133.179, with certain exceptions. The optional dairy ingredients permitted in § 133.179(d) are "...cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, albumin from cheese whey, and skim milk cheese for manufacturing." Milk Protein Concentrate is not listed as an optional dairy ingredient in § 133.179(d) and is not listed as an exception in § 133.180(a). However, according to the Work Order for  brand Pasteurized Process Cheese Spread with Jalapeños, 36 pieces/case, 12 ounces/piece, this product includes Milk Protein Concentrate.

The use of Milk Protein Concentrate in these products constitutes a violation of Section 403(g)(1) of the Act because the products are represented as foods for which standards of identity have been prescribed by regulation and the use of Milk Protein Concentrate in these products does not conform to the standards.

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 a reasonable time within which the corrections will be completed.

Failure to make prompt corrections may result in further enforcement action, including seizure and injunction, being initiated by the Food and Drug Administration (FDA).

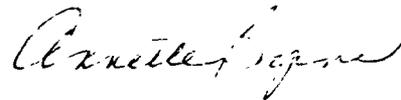
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This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling. As president, it is your responsibility to ensure that all products distributed 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) 334-4100 ext. 124.

Sincerely,



Annette Byrne
Acting Director
Minneapolis District

TSW
TSW/ccl