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December 18, 2002

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863**WARNING LETTER**
CHI-6-03**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Ms. Betsy D. Holden, President & CEO
Kraft Foods North America, Inc.
NF 301
Three Lakes Drive
Northfield, IL 60062

Dear Ms. Holden:

The Food and Drug Administration (FDA) recently conducted inspections of your facilities located in Champaign, IL; New Ulm, MN; and Springfield, MO. These inspections were 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).

Our inspectional observations and a review of certain labeling collected during the subject inspections found serious violations of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Section 133, Subpart B – Requirements for Specific Standardized Cheese and Related Products (21 CFR, Section 133, Subpart B).

Your firm's "Kraft Singles American Pasteurized Process Cheese Food," "Kraft Singles Sharp Cheddar Pasteurized Process Cheese Food," and "Kraft Singles Swiss Pasteurized Process Cheese Food" products are misbranded within the meaning of Section 403(g)(1) of the Act in that they purport to be or are represented as a food, namely pasteurized process cheese food, for which a definition and standard of identity has been prescribed in 21 CFR 133.173, and the products do not conform to the definition and standard. Milk protein concentrate is not listed in § 133.173(d) as one of the optional dairy ingredients that may be used in pasteurized process cheese food.

Your firm's "Kraft Velveeta Pasteurized Process Cheese Spread" product is misbranded within the meaning of Section 403(g)(1) of the Act in that it purports to be or is represented as a food, namely pasteurized process cheese spread, for which a definition and standard of identity has been prescribed in 21 CFR 133.179, and the product does not conform to the definition and standard. Milk protein concentrate is not listed in § 133.179(d) as one of the optional dairy ingredients that may be used in pasteurized process cheese spread.

These products declare milk protein concentrate in their ingredients listings. Milk protein concentrate (MPC) is not listed as an optional dairy ingredient in any of the standardized cheese products governed by a standard of identity, and therefore standardized cheese products are not permitted to contain MPC as an ingredient.

Further details of the inspections documenting these violations, and our observations, follow below:

- › On July 8, 9, 10, 12, and 17, 2002, we conducted an inspection of your facility located in Champaign, IL. During the inspection, our Chicago District investigator witnessed the use of dry milk protein concentrate during the production of "Kraft Singles American Pasteurized Process Cheese Food." Specifically, on July 9, 2002, our investigator observed the addition of [REDACTED] during the manufacture of "Kraft Singles American Pasteurized Process Cheese Food." Our investigator collected labeling for this finished product, which declares milk protein concentrate in the ingredients listing.

Product labels for "Kraft Singles Sharp Cheddar Pasteurized Process Cheese Food" and "Kraft Singles Swiss Pasteurized Process Cheese Food," both of which declare milk protein concentrate in their ingredient listings, were also collected by our investigator for review during the subject inspection.

- › On July 30, 31, and August 1, 2, 2002, we conducted an inspection of your facility located in New Ulm, MN. During that inspection, our Minneapolis District investigators witnessed the use of dry milk protein concentrate during the production of "Kraft Singles American Pasteurized Process Cheese Food."

Specifically, on July 30, 2002, our investigators observed the addition of [REDACTED] during the manufacture of "Kraft Singles American Pasteurized Process Cheese Food." Our investigators collected labeling for this finished product, which declares milk protein concentrate in its ingredients listing.

- › On August 26, 27, 28, 29, and 30, 2002, we conducted an inspection of your facility located in Springfield, MO. During that inspection, our Kansas City District investigators witnessed the use of dry milk protein concentrate during the production of "Kraft Singles American Pasteurized Process Cheese Food." Specifically, our investigators observed the combining of [REDACTED] with whey, and whey protein concentrate with water, to create a batch of wet mix. The wet mix was then added during the manufacture of "Kraft Singles American Pasteurized Process Cheese Food." Our investigators collected labeling for this finished product, which declares milk protein concentrate in its ingredients listing.

Product labels for Kraft Velveeta Pasteurized Process Cheese Spread, which declare milk protein concentrate in the ingredient list, were also collected by our investigator for review during the subject inspection.

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.

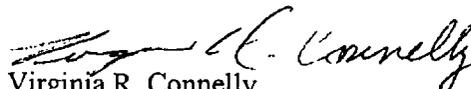
The above is not intended to be an all-inclusive list of deficiencies at your facility. As a food manufacturer, it is your responsibility to assure that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure of these misbranded products and/or injunction of your facility to prevent continued violation of the Act.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to correct these violations, including an explanation of steps that will be taken to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be sent to Patrick J. Brown, Compliance Officer, at the address listed in the letterhead.

Sincerely,


Virginia R. Connelly
Acting District Director