



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

June 10, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 25

Donald M. Hutchinson
President
Larsen's Bakery, Inc.
3311 Washington Avenue
Racine, Wisconsin 53405

Dear Mr. Hutchinson:

On February 20 and 21, 2003, the Food and Drug Administration conducted an inspection of your facility at 3311 Washington Ave., Racine, WI. During this inspection, our investigator collected label samples from your firm's almond variety of "Original Danish Kringle." These products are misbranded under Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) because the label fails to list all of the ingredients by their common or usual names as required by Title 21, Code of Federal Regulations, Section 101.4(a)(1). Specifically, the ingredients in the fillings and the margarine, each of which contains two or more ingredients, are not declared in accordance with the requirements of 101.4(b)(2). We also note that the label includes butter as an ingredient; however, butter is not present in the product.

The filling is made from one of four pastes; some of these pastes are made with almonds or peanuts. The declaration of almonds and peanuts is of particular concern. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to allergenic substances in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergenic responses are milk, eggs, fish, crustaceans, tree nuts (e.g., almonds), wheat, peanuts, soybeans, and derivatives of these products.

Your kringles packaged for mail order/ fundraising are misbranded under Section 403(e)(2) of the Act in that the labels fail to declare an accurate statement of the quantity of contents in terms of weight, measure, or numerical count.

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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.

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.

Additionally, your product labels indicate that the kringles contain "FD&C YEL #5," which is an unrecognized abbreviation for certified color FD&C Yellow 5. A certified color additive must be individually declared in the ingredient statement by its common or usual name (e.g., FD&C Yellow No. 5), in accordance with 21 CFR 101.22(k)(1). The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Yellow 5).

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, which may include product brochures, product catalogs, newsletters and Internet web sites, as applicable. As owner, 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
TSW