



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

January 22, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 14

John C. Lewis
President
Country Home Bakery & Deli, Inc.
20 North Lake Street
Forest Lake, Minnesota 55025

Dear Mr. Lewis:

On August 29 and September 2-4, 2003, an investigator with the Food and Drug Administration conducted an inspection of your facility at 20 North Lake Street, Forest Lake, Minnesota. During this inspection, the investigator collected label samples for your White Bread, Italian Bread, Pumpernickel Bread, Kaiser Rolls, and Turkey Buns. Our review of your firm's operations and product labels reveals these products to be misbranded within the meaning of Sections 403(i)(2) and 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) and implementing regulations contained within Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). These regulations may be found on our website at www.fda.gov.

Two of these products, "Turkey Buns" and "White Bread," are misbranded within the meaning of Section 403(i)(2) of the Act in that they are fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient in the product (21 CFR 101.4).

The "Turkey Buns" are labeled with an ingredient listing as follows: "Flour, Water, Sugar, Nonfat Dry Milk, Shortening, Yeast, Salt." Our investigator observed that this finished product was being made with the "~~~~~ Bun Base" distributed by ~~~~~. The label for this base shows numerous ingredients not included in the "Turkey Buns" label, including soy flour.

The "White Bread" is labeled with an ingredient listing as follows: "Flour, Water, Sugar, Nonfat Dry Milk, Shortening, Yeast, Salt." According to the Form 463a affidavit which your production manager signed, this finished product is made with

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the " Bread Base" distributed by  The label for this base shows numerous ingredients not included in the "White Bread" label, including soy flour.

Soy flour is made from soy, a known allergen. Undeclared ingredients that are known allergens are of particular concern to the agency. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance 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 allergic responses are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products.

Your White Bread, Italian Bread, Pumpernickel Bread, Kaiser Rolls, and Turkey Buns are misbranded within the meaning of Section 403(q)(1) of the Act in that their labels fail to bear nutrition labeling as required by 21 CFR 101.9, and these products are not exempt from this requirement under Section 403(q)(5) of the Act.

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 or ingredient labeling. As owner, it is your responsibility to ensure that all products manufactured by your firm are in compliance with the Act and its implementing regulations.

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.

In addition, we note that the Patent Flour used in the finished products addressed in this letter is labeled as "bleached, bromated, enriched." While the label of the flour fails to bear an ingredient listing, the standard of identity for bleached, bromated, and enriched flour is defined in 21 CFR 137.160 (covering enriched bromated flour), and 21 CFR 137.105 (covering optional bleaching ingredients). According to 21 CFR 101.4(b)(2), this flour would be a multi-component ingredient, containing potassium bromate, thiamin, riboflavin, among other ingredients, each of which must be declared in the ingredient listing for the finished product. You should correct the declaration of flour in the ingredient listings the next time these product labels are updated.

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. Your response should include revised labels. 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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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,

A handwritten signature in cursive script that reads "W. Charles Becoat".

W. Charles Becoat
Director
Minneapolis District

TSW/ccl
RLy