



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

March 16, 2004

Warning Letter No. 2004-NOL-17

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. William J. Wilson, Co-Owner
Mrs. Valerie Wilson, Co-Owner
Tennessee Cheesecake Company
2411 Crestmoor Road
Nashville, Tennessee 37215

Dear Mr. and Mrs. Wilson:

On December 9, 2003, an investigator with Food and Drug Administration conducted an inspection of your facility at 2411 Crestmoor Road, Nashville, Tennessee. During this inspection, the investigator collected label samples of your firm's Tennessee Cheesecake Brownie Swirl, Chocolate Swirl, Pumpkin, Cherry Swirl, and Original. Our review of your labels found your products to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, *Code of Federal Regulations* (CFR), Part 101. These regulations may be found on the Internet through links on the FDA homepage, www.fda.gov.

Your cheesecakes are misbranded under Section 403(i)(2) of the Act, because the products are made from two or more ingredients and the labels do not bear the common or usual name of each ingredients as required by 21 CFR 101.4(b)(2). For example, the cream cheese and graham crackers each contain two or more ingredients; however, the ingredient statement does not include the sub-components of each of these ingredients. The requirement may be met by either parenthetically listing the component ingredient after the common or usual name of the main ingredient, or by listing the component ingredients without listing the ingredients themselves. Under the first alternative, the component ingredients must be listed in descending order of predominance within the parenthesis; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

We also note that the vegetable oil ingredient in the "Brownie Swirl" cheesecake is not declared by its specific or usual name (e.g., soybean oil), as required by 21 CFR 101.4(b)(14).

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.

The above noted observations are not intended to be an all-inclusive list of existing deficiencies. It is your responsibility to assure compliance with all requirements of the Act, including such basic and obvious violations as are listed above.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Please respond directly to Kari L. Batey, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217 or telephone (615) 781-5380, extension 112.

Sincerely,


Patricia K. Schafer
Acting Director, New Orleans District