



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401  
Telephone: (612) 758-7114  
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May 24, 2006

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 06 - 26

George Haugo  
Vice President General Manager  
PepsiAmericas  
Northwest Division Dakota Regions  
4314 20th Avenue South  
Fargo, North Dakota 58103

Dear Mr. Haugo:

An inspection of your DakBev, LLC, dba Vending America facility (Vending America) located at 2700 Seventh Avenue N, Fargo, North Dakota, was conducted by an investigator from the Food and Drug Administration (FDA) on February 22-23 and 27, 2006. This inspection verified that your firm manufactures and distributes ready-to-eat food products. Labeling for some of your products and ingredients was collected and a review of that labeling found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101- Food Labeling. You can find the Act and FDA's regulations through links on FDA's Internet homepage at <http://www.fda.gov>.

Your Blueberry Coffee Cake (6 oz) product is adulterated under section 402(c) of the Act [21 U.S.C. 342(c)] because it bears or contains a color additive that is unsafe within the meaning of section 721(a) of the Act [21 U.S.C. 379(e)]. Section 721(a) deems a color additive to be unsafe unless its use is in conformity with the color additive's listing regulation. The listing regulation for FD&C Yellow No. 5, a color additive in the Blueberry Coffee Cake, requires that the color be specifically declared in the ingredient list on the label of foods for human use [21 CFR 74.705(d)(2)].

Your Chicken Salad Sandwich (6 oz), Ham Cheese Muffin (5.5 oz), Chicken Fajita Submarine (11 oz), and Blueberry Coffee Cake (6 oz) products are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. 343(i)(2)] because they are fabricated from two or more ingredients and fail to declare the common or usual name of each ingredient as specified under 21 CFR 101.4; for example:

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- Your Chicken Salad Sandwich is labeled to contain, in part: "...SALADDRESSING [sic], WHITE OR WHEAT BREAD...." The label we obtained for the salad dressing ingredient identifies several sub-ingredients including, in part: "...WATER, SOYBEAN OIL...EGG YOLKS, SALT...." In addition, white bread is a multi-ingredient food. The sub-ingredients in the bread and salad dressing are not listed on the finished product label.
- Your CHICKEN Fajita Submar (Submarine sandwich) is labeled to contain, in part: "...AMERICAN CHEESESWISS [sic] CHEESE...." American cheese and Swiss cheese are multi-ingredient foods that consist of milk, among other sub-ingredients. The label of the finished product fails to declare the sub-ingredients of the American cheese and Swiss cheese. The label of this product also fails to declare the presence of the fajita seasoning mix, which consists of several ingredients, including soybeans and wheat. Finally, the label fails to declare the oil ingredient in the product by its common or usual name. The ingredient statement lists "liquid oil," but does not specify the type of oil as required by 21 CFR 101.4(b)(14).
- Your Ham Cheese Muffin has an ingredient statement which states, in part: "...WHIPPED BUTTER, EGG PATTY...." The labels we obtained for these two ingredients identify several sub-ingredients, which are not listed on your finished product label. Also, whipped margarine is incorrectly declared on the label of Ham Cheese Muffin as "whipped butter," which is a different ingredient.
- Your Blueberry Coffee Cake has an ingredient statement which states, in part: "ENRICHRED [sic] BLEACH FLOUR, WHEAT FLOUR, EGGS...." This product is manufactured using the cake portion (not the streusel) from a coffee cake mix which is labeled to contain various ingredients including enriched bleached flour (wheat flour, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), partially hydrogenated soybean and cottonseed oils, leavening, yellow 5, yellow 5 lake, yellow 6, and yellow 6 lake. Several of these sub-ingredients are not listed on your finished product label.

The requirement to list these component ingredients (or "sub-ingredients") may be met either by parenthetically listing the component ingredients after the common or usual name of the multi-component ingredient, or by listing the component ingredients without listing the multi-component ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

Your Chicken Salad Sandwich (6 oz) and Chicken Fajita Submarine (11 oz) products are further misbranded within the meaning of section 403(w) of the

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Act [21 U.S.C. 343(w)] in that the labels fail to declare all major food allergens present in those products, as required by section 403(w)(1). Section 201(qq) of the Act (21 U.S.C. 321(qq)) defines a major food allergen as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- (1) The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients (section 403(w)(1)(A) of the Act [21 U.S.C. 343(w)(1)(A)]), or
- (2) The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen (section 403(w)(1)(B) of the Act [21 U.S.C. 343(w)(1)(B)]).

Guidance on the allergen labeling requirements in section 403(w) may be found on FDA's web site at <http://www.fda.gov>.

Your food labels fail to declare the following major food allergens as specified by the Act:

- Egg: Your Chicken Salad Sandwich contains egg, which is a sub-component of the salad dressing.
- Wheat and soy: Your CHICKEN Fajita Submar (Submarine sandwich) contains wheat and soy, which are sub-components of the fajita seasoning mix.

This letter is not meant to be an all-inclusive list of deficiencies that may exist in any of your product labeling or at your facility. It is your responsibility as top management to take prompt action to correct these violations, to establish procedures whereby such violations do not recur, and to review your operations and your product labels to ensure compliance with all applicable laws and regulations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

In addition to the violations described above, FDA has the following comments concerning the labeling of your products:

- The ingredient statement for your Blueberry Coffee Cake declares the presence of "Blue 5." There is no listing regulation for a certified color

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additive whose name could be abbreviated to Blue 5. If the Blueberry Coffee Cake contains a color additive that is not listed for use in food, the product would be further adulterated under section 402(c) of the Act. Alternatively, if the Blueberry Coffee Cake contains another color additive that is incorrectly declared as Blue 5, the product would be further misbranded under section 403(i)(2) of the Act for failing to declare that color additive by its common or usual name.

- Under 21 CFR 101.2(e), information required to be on the label of a food must appear without intervening material. Some of your food products are labeled with ingredient statements that contain intervening material; for example, the ingredient statement for your Ham Cheese Muffin includes the words "MIRCOWAVE [sic] 20SECS TO WARM" between the names of two ingredients.
- Your ingredient statements contain misspelled words, missing spaces and missing punctuation that affect the legibility of the ingredient statement (see section 403(f) of the Act [21 U.S.C. 343(f)]).
- Your Chicken Salad Sandwich (6 oz), Ham Cheese Muffin (5.5 oz), Blueberry Coffee Cake (6 oz), and Chicken Fajita Submarine (11 oz) products fail to bear the complete place of business of your Vending America facility. Your products bear a street address, but do not include the city, State, and ZIP code as required by 21 CFR 101.5(d).
- Your CHICKEN Fajita Submar sandwich label declares American cheese and Swiss cheese. Milk is a required ingredient of American and Swiss cheese and is a major food allergen that must be declared in accordance with section 403(w) of the Act [21 U.S.C. 343(w)].
- The labels of your Ham Cheese Muffin and Blueberry Coffee Cake products bear "Contains" statements that do not list the food sources of all of the major allergens contained in each food, as required by section 403(w)(1)(A) of the Act [21 U.S.C. 343(w)(1)(A)].


Finally, we note that Keith Ketcham of Vending America submitted a letter dated March 13, 2006, with revised draft labels for the four products cited in this letter. We have reviewed the labels but are unable to comment on them because they do not appear to be complete. For instance, all four ingredient statements end abruptly with a comma, and several main ingredients appear to be missing. For example, the Ham Cheese Muffin does not include the egg patty ingredient, and the Blueberry Coffee Cake is now labeled as Coffeecake and does not include any blueberry ingredients. It appears that the ingredient statements are incomplete, they are incorrect, or there have been formula changes. If you would like FDA to comment on your revised draft labels, please correct and resubmit them.

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You should notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated on the letterhead.

Sincerely,

  
W. Charles Becoat  
Director  
Minneapolis District

TSW/ccl