



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
FAX: (612) 334-4142

July 18, 2006

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 06 - 29

Joseph A. Berg
Owner
Royalston Foods dbā Royalston Desserts
69 Empire Drive
St. Paul, Minnesota 55103-1856

Dear Mr. Berg:

Investigators from the Food and Drug Administration (FDA) conducted an inspection of your facility located at 69 Empire Drive, St. Paul, Minnesota, on April 13-14, 17, 20 and 25, 2006. During the inspection, our investigators collected labels from several of your products. Our review of your product labels found that several of your products violate the Federal Food, Drug, and Cosmetic Act (the Act) and FDA regulations in Title 21, Code of Federal Regulations (21 CFR). You may find the Act and FDA regulations in the CFR through links on FDA's home page at www.fda.gov.

Your Gourmet M&M's® Frozen Cookie Dough (3 lbs) 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 the color additive FD&C Yellow No. 5 requires that this color be specifically declared in the ingredient list on the label of foods for human use [21 CFR 74.705(d)(2)]. According to information you provided to FDA during the inspection, FD&C Yellow No. 5 is an ingredient of the M&M's used in your Gourmet M&M's® Frozen Cookie Dough, but the label of your product does not list FD&C Yellow No. 5 as an ingredient.

Your Gourmet Oatmeal-Raisin Frozen Cookie Dough (3 lbs), Gourmet M&M's® Frozen Cookie Dough (3 lbs), and Gourmet Macadamia Nut Frozen Cookie Dough (3 lbs) products are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. 343(i)(2)] in that they are fabricated from two or more ingredients, but the product labels fail to declare the common or usual name of each ingredient as specified in 21 CFR 101.4. For example:

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- Your product Gourmet Oatmeal-Raisin Frozen Cookie Dough (3 lbs) is labeled to contain "[b]leached enriched wheat flour (wheat flour, folic acid, niacin, iron, thiamine, mononitrate, riboflavin), sugar, vegetable shortening (partially hydrogenated soybean oil with added mono and diglycerides), raisins, oatmeal, water, molasses, glucose, whole eggs, milk powder, sodium bicarbonate, salt, spices, natural and artificial flavors." However, according to the "Formula and Batch Sheet" for the Oatmeal Raisin Cookie Dough that you provided during the inspection, this product includes margarine as an ingredient. The label for your margarine ingredient identifies sub-ingredients that are not listed on your finished product label as required by 21 CFR 101.4(b)(2), such as partially hydrogenated cottonseed oil and soy lecithin. Further, the formula for Gourmet Oatmeal-Raisin Frozen Cookie Dough also lists cake flour and pastry flour, but these ingredients are not listed on your finished product label.
- Your product Gourmet M&M's® Frozen Cookie Dough (3 lbs) is labeled to contain "[b]leached enriched wheat flour (wheat flour, folic acid, niacin, iron, thiamine, mononitrate, riboflavin), sugar, vegetable shortening (partially hydrogenated soybean oil), M&M's®, butter, corn syrup, water, pasteurized whole eggs, salt, sodium bicarbonate, natural and artificial flavors." However, the M&M's® label we obtained during the inspection identifies sub-ingredients, including: "[m]ilk chocolate (sugar, chocolate, cocoa butter, skim milk, milkfat, lactose, soy lecithin, salt, artificial flavors), sugar, cornstarch, less than 1%-corn syrup, gum acacia, coloring (includes red 40 lake, yellow 6, yellow 5, red 40, blue 1 lake, blue 2 lake, blue 1, blue 2, yellow 5 lake, yellow 6 lake), dextrin." Some of these sub-ingredients are not listed on your finished product label as required by 21 CFR 101.4(b)(2). Further, the formula for Gourmet M&M's® Frozen Cookie Dough also lists cake flour, pastry flour, and brown sugar, but these ingredients are not listed on your finished product label.

For your information, under CFR 101.22(k)(1), a color additive subject to certification under Section 721(c) of the Act must be declared by the name specified in the color additive's listing regulation in part 74 or part 82 of 21 CFR. The name of the color additive may be abbreviated to omit the "FD&C" prefix and the term "No.", as in the above list.

- Your Gourmet Macadamia Nut Frozen Cookie Dough (3 lbs) is labeled to contain "[b]leached enriched wheat flour (wheat flour, folic acid, niacin, iron, thiamine, mononitrate, riboflavin), sugar, water, corn syrup, white chocolate, macadamia nuts, eggs, salt, bicarbonate of soda, butter flavor, vegetable shortening (partially hydrogenated soybean oil with mono and diglycerides), vanilla, natural and artificial flavors." However, the label provided during the inspection for the "Wavy Drops" ingredient used in this product lists sub-ingredients, including: "[s]ugar, partially hydrogenated palm kernel oil, reduced mineral whey powder, non fat dry milk solids, anhydrous dextrose, soya [sic] lecithin (an emulsifier), salt,

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and artificial flavor.” Some of these sub-ingredients are not listed on your finished product label as required by 21 CFR 101.4(b)(2). Further, according to the “Formula and Batch Sheet” for this product that you provided during the inspection, Gourmet Macadamia Nut Frozen Cookie Dough includes margarine as an ingredient. The label for your margarine ingredient identifies sub-ingredients that are not listed on your finished product label, such as partially hydrogenated cottonseed oil and soy lecithin. Additionally, the formula for Gourmet Macadamia Nut Frozen Cookie Dough also lists cake flour, pastry flour, and brown sugar, but these ingredients are not listed on your finished product label.

The requirement to list sub-ingredients (i.e., component ingredients of multi-component foods used as ingredients in the finished product) 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.

Further, your products Gourmet Macadamia Nut Frozen Cookie Dough (3 lbs) and Gourmet M&M's® Frozen Cookie Dough (3 lbs) are misbranded under section 403(k) of the Act in that the labels fail to declare the presence of artificial color. The product formulation sheets for both products list caramel color. Although caramel color and other color additives not subject to certification need not be declared by name, 21 CFR 101.22(k)(2) requires that they be declared as, e.g., “artificial color” or “color added.”

Further, your products are also misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)] in that their labeling is false or misleading because their ingredient statements do not accurately represent the ingredients used in these products. For example, the ingredient statements for your Gourmet Oatmeal-Raisin Frozen Cookie Dough (3 lbs), Gourmet M&M's® Frozen Cookie Dough (3 lbs), and Gourmet Macadamia Nut Frozen Cookie Dough (3 lbs) products declare that these products contain vegetable shortening. However, according to the “Formula and Batch Sheet” documents you provided during the inspection, vegetable shortening is not used as an ingredient in these products. In addition, the ingredient statement for Gourmet M&M's® Frozen Cookie Dough declares that the product contains butter; however, butter is not present in the product according to the “Formula and Batch Sheet” for this product, which instead lists margarine as an ingredient.

Further, your Gourmet M&M's® Frozen Cookie Dough (3 lbs) and Gourmet Macadamia Nut Frozen Cookie Dough (3 lbs) products are misbranded within the meaning of Section 403(w) of the 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 the major food

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allergens 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)]).

More information on the allergen labeling requirements in section 403(w) may be found on FDA's website at www.cfsan.fda.gov/~dms/wh-argy.html.

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

- Milk: Gourmet M&M's® Frozen Cookie Dough (3 lbs) contains skim milk, which is a sub-ingredient of the M&M's used as an ingredient in the product.
- Milk: Gourmet Macadamia Nut Frozen Cookie Dough (3 lbs) contains reduced mineral whey powder and non fat dry milk solids, which are sub-ingredients of the "M&M's Drops" used as an ingredient in the product.

This letter is not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility as top management to ensure that your establishment is in compliance with all requirements of the Act and FDA regulations.

Failure to promptly correct these deviations may result in regulatory action without further notice. Such action may include seizure and injunction.

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

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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,

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

W. Charles Becoat
Director
Minneapolis District

TSW/ccl