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DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER
08-PHI-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 16, 2007

Michael Edelson, President and Owner
Fresh Made Incorporated
810-20 Bleigh Avenue
Philadelphia, PA 19111-3016

Dear Mr. Edelson:

We inspected your food manufacturing facility, located at 810-20 Bleigh Avenue, Philadelphia, PA on May 15 – 16, 2007. During the inspection, we collected physical samples of your product Happy Kids Strawberry Farmer's Cheese and TBOPOR GecapaGckuū Farmer Cheese. We also collected labeling for the above products, as well as for Happy Kids Peach Farmer's Cheese, Slender Cow, and Kopobka Sweet Whipped Butter. Our review of your labeling and other evidence collected by the investigator indicates serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR). You can find copies of the Act and FDA's regulations through links on FDA's Internet page at www.fda.gov.

Your Happy Kids Strawberry Farmer's Cheese, Happy Kids Peach Farmer's Cheese, and Slender Cow 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, including sub-ingredients (ingredients of an ingredient in the finished product), as required in 21 CFR 101.4(a) and 101.4(b)(2). See below for examples:

- The label of your Happy Kids Strawberry Farmer's Cheese product lists "Strawberry" as an ingredient. We documented during the inspection that the label of the strawberry topping used to make your product declares sub-ingredients in addition to strawberries; however, these sub-ingredients are not listed in the ingredient statement on your finished product label (e.g., Starch, Water, Citric Acid, Xanthan Gum, Potassium Sorbate).

- The label of your Happy Kids Peach Farmer's Cheese product lists "Peach" as an ingredient. We documented during the inspection that the label of the peach topping used to make your product declares sub-ingredients in addition to peaches; however, these sub-ingredients are not listed in the ingredient statement on your finished product label (e.g., Starch, Water, Citric Acid, Xanthan Gum, Potassium Sorbate).
- Happy Kids Strawberry Farmer's Cheese and Happy Kids Peach Farmer's Cheese contain certified color additives that are not declared in the ingredient list. During the inspection of your firm, we documented that Happy Kids Strawberry Farmer's Cheese is made with [REDACTED] Strawberry RTU Topping and Happy Kids Peach Farmer's Cheese is made with [REDACTED] Peach RTU Topping. Each of these fruit toppings lists "Red #40" in their labels' respective ingredient statements, and the strawberry topping also lists "Red #3." These ingredients are certified color additives [see 21 CFR 74.340 and 21 CFR 74.303, respectively]. Under 21 CFR 101.22(k)(1), a certified color additive must be individually declared in the ingredient statement by the name specified in the color additive's listing regulation (in this case, FD&C Red No. 40 and FD&C Red No. 3, respectively). The name of the color additive may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Red 40 and Red 3).
- Your Slender Cow product lists "Oleo" in the ingredient statement on the label. According to information provided by the plant manager during the inspection, the Slender Cow product is a mixture of butter and oleomargarine. Oleomargarine is a food for which a definition and standard of identity have been established by regulation [see 21 CFR 166.110]; therefore, under 21 CFR 101.3(b)(1) and 166.110(c), the ingredient list for the Slender Cow product must declare this ingredient by the name prescribed in that regulation (i.e., "oleomargarine" or margarine").

Further, your Happy Kids Strawberry Farmer's Cheese and Happy Kids Peach Farmer's Cheese products are misbranded within the meaning of section 403(k) of the Act [21 U.S.C. § 343(k)] because they contain undeclared artificial coloring. In addition to the certified color additives discussed above, the Happy Kids Strawberry Farmer's Cheese contains turmeric, an ingredient of the [REDACTED] Strawberry RTU Topping, and the Happy Kids Peach Farmer's Cheese contains annatto, an ingredient of the [REDACTED] Peach RTU Topping. Although turmeric, annatto, 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 Happy Kids Strawberry Farmer's Cheese and Happy Kids Peach Farmer's Cheese products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] because the labels are false or misleading in that the products are labeled as "All Natural," but in fact contain artificial coloring as defined in 21 CFR 101.22(a)(4).

Your Slender Cow product is misbranded under Section 403(i)(1) [21 U.S.C. § 343(i)(1)], in that the label fails to bear the common or usual name of the food. Under 21 CFR 102.5, the common or usual name of a food must accurately describe the basic nature of the food or its characterizing properties or ingredients. The name "Slender Cow" does not meet this requirement.

Further, your Slender Cow product is misbranded within the meaning of section 403(q) of the Act [21 U.S.C. § 343(q)] in that the Nutrition Facts panel fails to declare trans fat as required by 21 CFR 101.9(c)(2)(ii). The regulation requiring the declaration of trans fat went into effect on January 1, 2006 (see 68 FR 41433). You should review all of your product labels to ensure they comply with this regulation. For additional information on trans fat labeling, go to <http://www.cfsan.fda.gov/~dms/lab-cat.html#transfat>.

Allergen Labeling

Your Kopobka Sweet Whipped Butter is misbranded within the meaning of Section 403(w) of the Act [21 U.S.C. § 343(w)] in that the label fails to declare milk, a major food allergen present in this product, as required by section 403(w)(1). Section 201(qq) of the Act [21 U.S.C. § 321(qq)] defines as major food allergens 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:

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

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 food source from which the major food allergen is derived 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)]).

The allergen labeling requirements of section 403(w) can be accessed on our website at www.cfsan.fda.gov/~dms/algact.html. Further guidance and information on food allergens can be accessed on our website at <http://www.cfsan.fda.gov/~dms/wh-alrgy.html>.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and injunction.

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies in your products and their labeling. Other violations can also subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with all applicable statutes and regulations enforced by FDA.

In addition to the violations described above, we have the following comments concerning the labeling of your various products.

Your Happy Kids Strawberry Farmer's Cheese product, the Happy Kids Peach Farmer's Cheese product, the TBOPOR GecapaGckuñ Farmer Cheese product, the Slender Cow product, and the Kopobka Sweet Whipped Butter product do not meet the nutrition labeling format requirements in 21 CFR 101.9. For example, the type sizes in the nutrition label of the three Farmer's Cheeses do not meet the requirements in 21 CFR 101.9(d), and the ingredient statement for the Kopobka Sweet Whipped Butter and the Slender Cow products is located inside the "Nutrition Fact" panel. Under 21 CFR 101.9(c), no food components other than those listed in section 101.9(c) as mandatory or voluntary may be included within the "Nutrition Facts" panel.

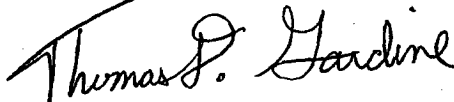
The first ingredient declared in the Happy Kids Farmer's Cheese products is "Cultured Pasteurized Grade A Milk." If this milk ingredient meets the standard of identity for "cultured milk" in 21 CFR 131.112(f), then it should be listed as "cultured milk."

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific things that you are doing to correct the violations described above. You should include in your response documentation for our evaluation of your corrective actions. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining violations.

Page 5 – Warning Letter Fresh Made, Inc., Philadelphia, PA

Your response should be sent to Robin M. Rivers, Compliance Officer, at the address noted above.

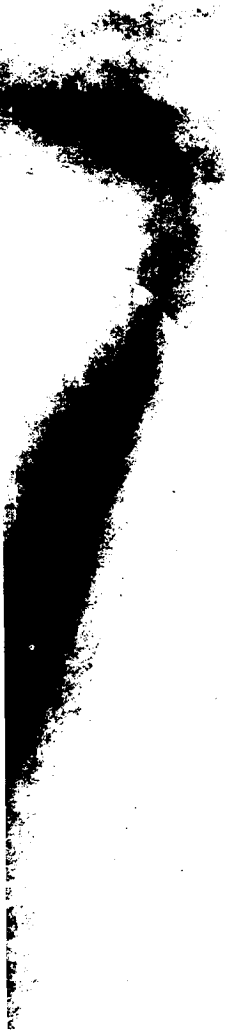
Sincerely,



Thomas D. Gardine
District Director
Philadelphia District Office

cc: Iyla Mandel, Corporate Vice President
Fresh Made Incorporated
810-20 Bleigh Avenue
Philadelphia, PA 19111-3016

Pennsylvania State Department of Agriculture
Bureau of Foods and Chemistry
2301 North Cameron Street
Harrisburg, PA 17120-9408
Attention: Sheri Morris



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MAY 11 1998
PHILADELPHIA DISTRICT OFFICE