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Inspections, Compliance, Enforcement, and Criminal Investigations

Cytosport Inc 6/29/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

Via UPS

Delivery Signature Requested

June 29, 2011

Mr. Michael Pickett
Chief Executive Officer and President
CytoSport, Inc.
4795 Industrial Way
Benicia, CA 94510

Re: FEI 3004427822

Dear Mr. Pickett:

The Food and Drug Administration (FDA) has reviewed the labels for your "Chocolate Muscle Milk Protein Nutrition Shake" (14 fl. oz.), "Vanilla Crème Muscle Milk Light Nutritional Shake" (4-8.25 oz. servings), and "Chocolate Peanut Caramel Muscle Milk" (5.57 oz.) products. Based on our review, we have concluded that these products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR Part 101). These products are misbranded within the meaning of section 403 of the Act [21 U.S.C. § 343]. You can find copies of the Act and these regulations through links on FDA's home page at <http://www.fda.gov>¹.

1. Your "Chocolate Muscle Milk Protein Nutrition Shake" and "Vanilla Crème Muscle Milk Light Nutritional Shake" products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labels are false or misleading. For example:

- These product labels prominently feature the word "MILK," however these products contain no milk. The actual statements of identity, "Protein Nutrition Shake" and "Nutritional Shake" are in significantly smaller and less prominent type than the words "MUSCLE MILK" on these product labels.
- These product labels include the statement "Contains No Milk" on the principal display panel; however, according to the ingredient statements, these products contain the following milk-derived ingredients: calcium and sodium caseinate, milk protein isolate, and whey. The allergen statement printed on both of these products states "This product contains ingredients derived from milk" The "Contains No Milk" statement could give consumers the impression that these products are free of milk-derived ingredients.

2. Your "Chocolate Muscle Milk Protein Nutrition Shake" and "Vanilla Crème Muscle Milk Light Nutritional Shake" products are misbranded within the meaning of section 403(g)(1) of the Act [21 U.S.C. § 343(g)(1)] because they purport to be a food for which a definition and standard of identity has been prescribed by regulation but they fail to conform to such definition and standard. Specifically, these products purport to be milk by prominently featuring the word "MILK" on the labels. Milk is a food for which a definition and standard of identity has been prescribed by regulation. The standard of identity for milk (21 CFR 131.110) describes milk as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows" and lists the vitamins and other ingredients that may be added. According to the ingredient list on your product labels, your products contain no milk and contain numerous ingredients not permitted by the standard; therefore, your products do not conform to the standard of identity for milk.

3. Your "Chocolate Muscle Milk Protein Nutrition Shake" and "Chocolate Peanut Caramel Muscle Milk" products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product labels and labeling bear nutrient content claims that are not authorized by regulation or fail to comply with the regulations that authorize nutrient content claims, nor are they authorized under section 403(r)(3)(C).¹ Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food misbrands a product unless the characterization of the level made in the claim uses terms which are defined in FDA regulations. For example:

- To bear the nutrient content claim "healthy," under 21 CFR 101.65(d)(2), foods: (1) must be "low fat" as defined in 21 CFR 101.62(b)(2) (total fat content of 3 g or less per Reference Amount Customarily Consumed (RACC)); (2) must be "low saturated fat" as defined in 21 CFR 101.62(c)(2) (saturated fat content of 1 g or less per RACC and no more than 15 percent of calories from saturated fat); (3) must not exceed the disclosure level for cholesterol set forth in 21 CFR 101.13(h) (60 mg cholesterol per RACC); (4) must contain at least 10 % of the Daily Value per RACC of one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, or fiber; and (5) must contain no more than 480 mg sodium per RACC and per labeled serving.

o The label of your "Chocolate Muscle Milk Protein Nutrition Shake" bears the claim "Healthy, Sustained Energy" in connection with the statements "Protein Nutrition Shake" and "25 g Protein." In addition, your webpage <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>² under the heading entitled "14-oz. Muscle Milk® Ready-To-Drink (RTD)" includes the claim "healthy sustained energy." Based on the Nutrition Facts panel, this product contains 9 g of fat per 414 mL serving. According to 21 CFR 101.12(b), Table 2, the RACC for beverages is 240 mL. Thus, your product contains 5 grams of fat per the RACC of 240 mL. Your product's fat content exceeds the 3 g of fat per RACC of food maximum in the "low fat" definition (21 CFR 101.62(b)(2)). Accordingly, this product does not meet the requirements for the use of the nutrient content claim "healthy" on food labeling (21 CFR 101.65(d)(2)).

o The label of your "Chocolate Peanut Caramel Muscle Milk" product bears the claim "25g Protein for Healthy, Sustained Energy" in connection with the claim "0g Trans Fat." In addition, your webpage <http://www.cytosport.com/products/muscle-milk/muscle-milk-bars>³ under the heading entitled "Muscle Milk® Bars" includes the claim "healthy sustained energy," in connection with the claims "loaded with 25 grams of high-quality muscle-source protein," and "no trans fats." Based on the Nutrition Facts panel, this product contains 11 g of fat and 8 g of saturated fat per 73 serving. According to 21 CFR 101.12(b), Table 2, the RACC for all other candies is 40 g. Thus, your product contains 6 grams of fat and 4.5 grams of saturated fat per 40 gram RACC. Your product's fat and saturated fat content exceeds the 3 g of fat per RACC of food maximum in the "low fat" definition (21 CFR 101.62(b)(2)) and the 1 g of saturated fat per RACC of food maximum in the "low saturated fat" definition (21 CFR 101.62(c)(2)). Accordingly, this product does not meet the requirements for the use of the nutrient content claim "healthy" on food labeling (21 CFR 101.65(d)(2)).

- Your "Chocolate Peanut Caramel Muscle Milk" product label bears the nutrient content claim "0g Trans Fat." This statement is a nutrient content claim provided for in 21 CFR 101.13(i). 21 CFR 101.13(h) requires that if a food contains a nutrient content claim and more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per RACC or per labeled serving, then that food must also bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: "See nutrition information for ____ content" with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., "See nutrition information for saturated fat content." However, your product contains a nutrient content claim and more than 4 g of saturated fat per labeled serving and per RACC, but fails to bear the required disclosure statement.

- Only the claims specified in 21 CFR 101.62 may be made for fat or fatty acids, and there are no nutrient content claims for carbohydrates authorized in the regulations. However, your "Chocolate Muscle Milk Protein Nutrition Shake," "Vanilla Crème Muscle Milk Light Nutritional Shake," and "Chocolate Peanut Caramel Muscle Milk" product labels bear the following unauthorized nutrient content claims:

o Your webpage <http://www.cytosport.com/products/muscle-milk/muscle-milk-bars>⁴ on the tab entitled "Benefits and Uses" under the heading entitled "Benefits of Using Muscle Milk® Bars" includes the unauthorized nutrient content claim "trans-fat free."

o Your "Chocolate Muscle Milk Protein Nutrition Shake" product label and your webpage <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>⁵ under the heading entitled "14-oz. Muscle Milk® Ready-To-Drink (RTD)" bear the unauthorized nutrient content claims "healthy fats" and "good carbohydrates."

o Your webpage <http://www.cytosport.com/products/muscle-milk/muscle-milk-light-ready-to-drink>⁶ under the heading entitled "14-oz. Muscle Milk® Light Ready-To-Drink" for your "Vanilla Crème Muscle Milk Light Nutritional Shake" product includes the unauthorized, undefined nutrient content claim "good fats."

4. Your "Chocolate Muscle Milk Protein Nutrition Shake," "Vanilla Crème Muscle Milk Light Nutritional Shake" and "Chocolate Peanut Caramel Muscle Milk" products are misbranded within the meaning of Section 403(q)(2)(A) of the Act [21 U.S.C. § 343(q)(2)(A)] because your nutrition labels for these products do not include the amounts of polyunsaturated and monounsaturated fats present in the product, as required by 21 CFR 101.9(c)(2)(iii) and (iv) when claims about fatty acids or cholesterol are made. Because your products bear the following claims about fatty acids, they must declare the amounts of polyunsaturated and monounsaturated fats present in these products:

- Your "Chocolate Peanut Caramel Muscle Milk" product label bears the claim "0g Trans Fat." Your webpage at

<http://www.cytosport.com/products/muscle-milk/muscle-milk-bars>⁷ under the heading entitled "Muscle Milk® Bars" bears the claim "no trans-fats." Your webpage at the same web address on the tab "Benefits and Uses" under the heading entitled "Benefits of Using Muscle Milk® Bars" bears the claim "trans-fat free."

- Your webpage for your "Chocolate Muscle Milk Protein Nutrition Shake" product <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>⁸ on the tab entitled "Benefits and Uses" under the heading entitled "Features" bears the claim "Medium-Chain Triglycerides (MCTs) are more likely metabolized for muscle energy and heat than stored as fat. Monounsaturated fats provide Essential Fatty Acids."
- Your webpage for your "Vanilla Crème Muscle Milk Light Nutritional Shake" product <http://www.cytosport.com/products/muscle-milk/muscle-milk-light-ready-to-drink>⁹ on the tab entitled "Benefits and Uses" under the heading entitled "Features" bears the claim "Trans-fat free Medium-Chain Triglycerides (MCT's) are more likely metabolized for muscle energy than stored as fat. Polyunsaturated and monounsaturated fatty acids canola oil and sunflower oil contain important essential fatty acids."

5. Your "Chocolate Muscle Milk Protein Nutrition Shake," "Vanilla Crème Muscle Milk Light Nutritional Shake," and "Chocolate Peanut Caramel Muscle Milk" products are misbranded within the meaning of Section 403(i) of the Act [21 U.S.C. § 343(i)]. For example:

- Your "Chocolate Peanut Caramel Muscle Milk" product label does not bear a statement of identity, in accordance with 21 CFR 101.3, which requires that the principal display panel of a food in package form shall bear as one of its principal features a statement of identity of the commodity and that such statement of identity shall be in terms of the name now or hereafter specified in or required by any applicable Federal law or regulation; or in the absence thereof, the common or usual name of the food; or in the absence thereof, an appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.
- The ingredients statements of your "Chocolate Muscle Milk Protein Nutrition Shake" and "Vanilla Crème Muscle Milk Light Nutritional Shake" products do not meet the requirements in 21 CFR 101(a)(1), which states that ingredients must be listed by common or usual name in descending order of predominance by weight, and do not meet the requirements in 21 CFR 101.4(b), which requires that the name of an ingredient shall be a specific name and not a collective (generic) name. However, these product labels list "vitamin mineral blend" in the ingredients statement and list the individual ingredients of your "vitamin mineral blend" in a separate statement below the ingredients statement.

This letter is not intended to be an all-inclusive review of your products and their labeling. It is your responsibility to ensure that all of your products comply with the Act and its implementing regulations. You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. Such action may include, but is not limited to, seizure or injunction.

In addition, we note that your webpage for "Vanilla Crème Muscle Milk Light Nutritional Shake" <http://www.cytosport.com/products/muscle-milk/muscle-milk-light-ready-to-drink>¹⁰ under the heading entitled "14-oz. Muscle Milk® Light Ready-To-Drink" does not meet the requirements to make relative claims. The webpage bears the claims "Light" and "lower in calories," but does not provide the identity of the reference food as required by 21 CFR 101.13(j)(1), or the percent (or fraction) that the calories were reduced in immediate proximity to the most prominent claim and does not provide quantitative information comparing the levels of calories in the product per labeled serving size with that of the reference food it replaces declared adjacent to the most prominent claim or to the nutrition label, as required by 21 CFR 101.13(j)(2) and 21 CFR 101.56(b)(3).

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct the violations cited above and to prevent similar violations in the future. Your response should include documentation such as revised labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Please send your reply to the attention:

Darlene Almogela
Director, Compliance Branch
U.S. Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502

If you have any questions regarding any issue in this letter, please contact Carl Lee, Compliance Officer at 510-337-6737, or by fax at (510) 337-6703.

Sincerely,

/s/

Barbara Cassens
District Director

¹ See <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm>¹¹

Links on this page:

1. <http://www.fda.gov>
2. <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>
3. <http://www.cytosport.com/products/muscle-milk/muscle-milk-bars>
4. <http://www.cytosport.com/products/muscle-milk/muscle-milk-bars>
5. <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>
6. <http://www.cytosport.com/products/muscle-milk/muscle-milk-light-ready-to-drink>
7. <http://www.cytosport.com/products/muscle-milk/muscle-milk-bars>
8. <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>
9. <http://www.cytosport.com/products/muscle-milk/muscle-milk-light-ready-to-drink>
10. <http://www.cytosport.com/products/muscle-milk/muscle-milk-light-ready-to-drink>
11. <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/DAModernizationActFDAMAClaims/default.ht>