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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
P.O. Box 25087  
6<sup>th</sup> Avenue & Kipling Street  
Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
FAX: 303-236-3100

July 1, 2005

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ref. # DEN- 05-14

Mr. Mark J. Callahan, President  
Blake Street Manufacturing, LLC  
dba Art Coco Chocolate Company  
2660 Walnut Street  
Denver, Colorado 80205-2231

Dear Mr. Callahan:

The Food and Drug Administration (FDA) conducted an inspection of your facility located at 2660 Walnut Street, Denver, Colorado on February 23 through 25, and April 4, 2005. Labeling for your products was collected and a review of that labeling indicates serious violations of the Federal Food, Drug and Cosmetics Act (the Act), the Fair Packaging and Labeling Act, and Title 21 of the Code of Federal Regulations (21 CFR), Part 101- Food Labeling. You can find the Act, the Fair Packaging and Labeling Act and FDA's food labeling regulations through links on FDA's Internet homepage at: <http://www.fda.gov>.

The products Petite Box, Small Ducks, Small Rubber Ducks, Large Rubber Ducks, Flower Pops, Decorated Eggs, Christmas Stocking, Gingerbread Man, and Snow Man are misbranded within the meaning of section 403(q)(1) of the Act in that the labels fail to bear nutrition labeling as required by 21 CFR 101.9.

The products Petite Box, Small Ducks, Small Rubber Ducks, Large Rubber Ducks, Flower Pops, Decorated Eggs, Christmas Stocking, Gingerbread Man, and Snow Man are misbranded within the meaning of section 403(i)(1) of the Act in that the principal display panels do not bear the common or usual name of the food, as required by 21 CFR 101.3(a) and (b).

The products Petite Box, Small Ducks, Small Rubber Ducks, Large Rubber Ducks, Flower Pops, Decorated Eggs, Christmas Stocking, Gingerbread Man, Snow Man and Large Chocolate Box

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are misbranded within the meaning of section 403(e)(1) of the Act in that the labels fail to identify the place of business of the manufacturer, packer, or distributor as required by 21 CFR 101.5(a).

For your information, we note that your Large Chocolate Box product does not bear the current name and address of your business, namely, Blake Street Manufacturing, LLC, dba Art Coco Chocolate Company, 2660 Walnut Street, Denver, Colorado 80205-2231. The name and place of business listed on your Large Chocolate Box product is Topographic Chocolate Co., 2601 Blake Street, Denver, Colorado. Yet, you informed us that Topographic Chocolate Company (TCC) had been dissolved in August of 2004.

The product Petite Box is misbranded under chapter III of the Act in that the net quantity of contents statement is not stated in a uniform location on the principal display panel of the label, as required by 15 U.S.C. 1453(a)(2) and 15 U.S.C. 1456(a) of the Fair Packaging and Labeling Act.

The products Christmas Stockings, Snowman, and Gingerbread Man are misbranded within the meaning of section 403(i)(2) in that they contain the color additives Red 3, Red 40, Blue 1 Lake, Yellow 5 Lake, and Yellow 6 Lake that are subject to certification, but the product labels fail to declare these colors by specific name, as required by 21 CFR 101.22(k)(1).

The above violations are not meant to be an all-inclusive list of deficiencies in your labeling or at your facility. You should 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, we note that the labels for your Art Coco <sup>TM</sup> Large Chocolate Box does not list each of the ingredients in the Dark Chocolate Coated Orange Cream, Dark Chocolate Coated Lemon Cream, Milk Chocolate Coated Chocolate Butter Creams, and Vanilla Butter Cream Milk Chocolate Coated with White String, that are randomly used to fill the chocolate box, as required by 21 CFR 101.4(a)(1). For example, the ingredient list does not include butterfat, partially hydrogenated palm kernel oil, apple nuggets (with calcium stearate, sulfur dioxide and sodium sulfite added as preservatives), tapioca starch, orange emulsion (with vegetable gums, propylene glycol, artificial color, and sodium benzoate added as a preservative), and cocoa powder found in the Dark Chocolate Coated Orange Cream. This requirement may be met by either parenthetically listing the component ingredients of each piece of candy after the common or usual name of each of the chocolate cream candies, or by listing the component ingredients of each of the candies without identifying the individual chocolate creams. 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 (i.e., the Large Chocolate Box).

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Further, we note that the ingredient statement for the Art Coco™ Large Chocolate Box lists ingredients (walnut, pecans, coconut, almond, honey, dried raspberries, unsalted butter and chocolate mass) that are not listed in the ingredient statement of the assorted chocolate creams that are used to fill the chocolate box.

We acknowledge that you have revised your labels for the products Flower Pops and Decorated Eggs so that the labels for these products now provide ingredient statements that declare “Yellow 5, 6 Lake, Red 3, 40, Blue 1 Lake.” In addition, the revised label for the Petite Box includes the ingredients “Yellow 5/6.” Please recognize that these labels must individually declare each of the certified colors used in the product (e.g., Yellow 5 Lake, Yellow 6 Lake, Blue 1 Lake, Yellow 5, Yellow 6, Red 3, Red 40, etc.) as required by CFR 101.4(a)(1) and 101.22(k)(1) rather than grouped together as you have done. We also note that the labels for the products Small Ducks and Large Ducks have been revised to include the certified colors “Yellow 5 Lake” and “Yellow 6 Lake” parenthetically after the term “artificial.”

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you have taken to correct the above-cited violations to the Act and the Fair Packaging and Labeling Act. For corrections that you cannot complete within the fifteen (15) working days, state the justification for the delay and your timeframe for completion. Please provide documentation of the corrections as they are made, including copies of any revised labels, and explain your plan for preventing such violations in the future.

Please direct your response to the Food and Drug Administration, Denver District, Attention: Ms. Shelly L. Maifarth, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Maifarth at (303) 236-3046.

Sincerely,



B. Belinda Collins  
District Director