



DEPARTMENT OF HEALTH AND HUMAN SERVICE

93425d
Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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July 24, 2002

WARNING LETTER NO. 2002-NOL-38

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mrs. Dian R. Sison, President
The Chocolate Box, Inc.
1212 Highway 589
Purvis, Mississippi 39475

Dear Mrs. Sison:

During April 10 & 15, 2002, investigators with the U.S. Food and Drug Administration (FDA) conducted an inspection of your candy manufacturing facility located at 1212 Highway 589, Purvis, Mississippi. The inspection was conducted to determine compliance with FDA's Current Good Manufacturing Practices (CGMPs) regulations, Title 21, *Code of Federal Regulations* (CFR), Part 110, and 21 CFR 101, Food Labeling. Our review of your labeling, collected during the inspection reveals your products to be in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act).

Our review of the labels disclosed the following:

- Your products, such as "Chocolate Peppermint Confetti," "Chocolate Lemon Confetti," and yellow rose candy labeled "Handmade Novelty Chocolate Candy" are all misbranded under Section 403(g) of the Act [21 U.S.C. § 343]. Each of these products purports to be a chocolate product by including "chocolate" on its label, but none meet the requirements to be labeled as chocolate under the standards of identity in 21 CFR 163 for standardized cacao products. Chocolate liquor, also known as chocolate, is defined in part as "the solid or semiplastic food prepared by finely grinding cacao nibs" [21 CFR 163.111(a)]. Your products labeled as chocolate and those listed above do not contain such an ingredient.
- Your products labeled as "white chocolate," such as those labeled "Pick of the Crop Dixie Snow Crispies and Crunchies covered in a blanket of White Chocolate" and "Dixie Snow," labeled "covered in a creamy pure white chocolate" are also misbranded under Section 403(g) of the Act because use of the term "white chocolate" requires a temporary marketing permit (TMP) under 21 CFR 130.17. Otherwise, because white chocolate does not contain the nonfat portion of the cacao nibs, but is labeled as chocolate, a product labeled as white chocolate is misbranded. In addition, your products labeled as "white chocolate" do not contain the fat (cocoa butter) from ground cacao nibs that would be necessary to obtain a TMP for white chocolate.

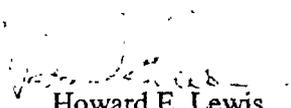
- The label of "Pick of the Crop Dixie Snow Crispies and Crunchies covered in a blanket of White Chocolate" is false and misleading in violation of Section 403(a) of the Act because it lists "chocolate" as an ingredient but does not contain chocolate, as evidenced by the ingredient list for "chocolate" on the label.
- Some of your products made from Candy Kote Wafers are misbranded within the meaning of Sections 403(k) and 403(i)(2) of the Act because the statement of ingredients for those products does not include the specific certified colors they contain. Specifically, the labels for the Candy Kote Wafers that you use to manufacture your products specified below list certified color additives, but you do not declare these certified color additives as part of the list of ingredients on your products:
 - ◆ Yellow colored tulips contain Yellow 5 lake
 - ◆ Violet colored tulips contain Blue 2 lake and Red 3
 - ◆ Green colored candies contain Blue 1 lake and Yellow 5 lake
 - ◆ Red colored candies contain Red #40 lake; and
 - ◆ Pink colored tulips contain Red 3.
- Your products labeled with the gold "The Chocolate Box" generic labels are misbranded within the meaning of 403(e)(2) of the Act because the label does not contain a statement of the quantity of contents.

The above-cited violations are not meant to be an all-inclusive list of deficiencies on your labels. Other labeling violations could also subject your firm and food to legal action. It is your responsibility to ensure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

We may take action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating. Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions taken to correct these deviations. You may wish to include in your response documentation, such as copies of your revised labeling or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you to explain the reason for your delay and state when you will correct any remaining deviations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the address above.

Sincerely,


Howard E. Lewis
Acting District Director
New Orleans District