

HFA-305



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC

MAY 30 2001

7450 '01 JUN -1 P124

Mr. Steve Genzoli  
Ghirardelli Chocolate Company  
1111 139<sup>TH</sup> Avenue  
San Leandro, California 94578

Dear Mr. Genzoli:

This is to acknowledge your letter of June 22, 2000, to the Food and Drug Administration (FDA), accepting the agency's invitation to participate in the extended temporary market testing of "white chocolate" that was granted to Hershey Foods Corporation (59 FR 67302, December 29, 1994). The amendment will allow for the market test of another product that contains white chocolate. The product will bear the name "Ghirardelli White Chocolate Baking Bar."

The white chocolate component of the product differs from standardized chocolate products in that it is prepared without the nonfat components of the ground cacao nibs, but contains the fat (cocoa butter) expressed from the ground cacao nibs. In all other respects, the white chocolate would conform to the cacao product standards.

Relying on the representations made in your application, we are hereby granting permission to make interstate shipments, for market testing purposes of 120,365 pounds (54,587 kg) of new test product. The product will be manufactured at Ghirardelli Chocolate Company, 1111 139<sup>th</sup> Avenue, San Leandro, California 94578 and will be distributed throughout the United States.

The draft label that you submitted for the test food is acceptable for the purpose of this market test. A finished label must be submitted to the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), before the product is shipped in interstate commerce: h of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR Part 101.

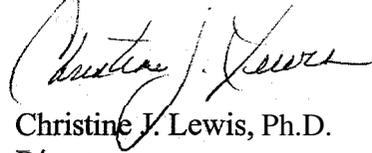
While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of "Ghirardelli White Chocolate Baking Bar" covered by this permit on the grounds that the food fails to comply with the standards of identity for certain chocolate

93P-0310

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products, e.g., chocolate liquor (21 CFR 163.111), sweet chocolate (21 CFR 163.123), milk chocolate (21 CFR 163.130), buttermilk chocolate (21 CFR 163.135), skim milk chocolate (21 CFR 163.140), or mixed dairy product chocolates (21 CFR 163.145).

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Christine J. Lewis".

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition



GHIRARDELLI CHOCOLATE COMPANY

June 22, 2000

Felicia Satchell  
Chief, Food Standards Branch  
Office of Food Labeling (HF-158)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW.  
Washington, DC 20204

Re: Notification pursuant to 21 CFR 130.77 of Participation in Extended Market Test of White Chocolate Deviating from the Standard of Identity in 21 CFR 163.111 (chocolate liquor), 163.123 (sweet chocolate), 163.135 (buttermilk chocolate), 163.140 (skim milk chocolate), or 163.145 (mixed dairy product chocolate).

Dear Ms. Satchell:

In accordance with 21 CFR 130.17(i), and notice appearing in the FEDERAL REGISTER of 58 Fed. Reg. 59,050 (November 5, 1993), (Docket No. 93P-0310), pertaining to an extension of a temporary permit for market testing White Chocolate, Ghirardelli Chocolate Company hereby notifies the Food and Drug Administration that the Company accepts the invitation to participate in the extended market test of White Chocolate.

1. The name and address of the applicant is: Ghirardelli Chocolate Company, 1111 139<sup>th</sup> Avenue, San Leandro, Ca 94578.
2. The White Chocolate product will be manufactured at Ghirardelli Chocolate Company, 1111 139<sup>th</sup> Avenue, San Leandro, Ca 94578.
3. The probable amount of test product to be distributed annually is 120,365 pounds of the test product. The proposed amount of the test product is the smallest amount of product that could be marketed due to processing limitations. The amount of test product shall be no more than the amount specified in the FEDERAL REGISTER notice inviting participation in the extended temporary market test.
4. The areas of distribution are all 50 states.
5. The White Chocolate referred to above deviates from the U.S. Standard of Identity for 21 CFR 163.111 (chocolate liquor), 163.123 (sweet chocolate), 163.130 (milk chocolate), 163.135 (buttermilk chocolate), 163.140 (skim milk chocolate), 163.145 (mixed dairy product chocolate), in that White Chocolate is the solid or semi-plastic food prepared by intimately mixing and

grinding cocoa butter with one or more nutritive carbohydrate sweeteners and one or more of the optional dairy ingredients specified in 21 CFR 163. It contains not less than 20 percent cocoa butter, not less than 14 percent of total milk solids, not less than 3.5 percent of milk fat, and not more than 55 percent of nutritive carbohydrate sweetener. It may also contain emulsifying agents, spices, natural and artificial flavorings and other seasonings, and antioxidants approved for food use.

6. An accurate draft of the proposed label for each brand and container size to be market tested is attached. Before the product is shipped in interstate commerce, finished labels complying with the applicable food labeling requirements in 21 CFR 101 and 130, will be submitted to the Office of Food Labeling (HF-158), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C Street, SW., Washington, DC 20204.

Ghirardelli Chocolate Company understand that any permit to market test White Chocolate expires either on the effective date of a final rule for any proposal to establish a new standard of identity for White Chocolate which may result from the petition, or 30 days after termination of such proposal.

Sincerely yours,



Steve Genzoli

encl.



GHIRARDELLI CHOCOLATE COMPANY

April 24, 2001

Loretta Carey  
Office of Nutritional Products, Labeling & Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

RE: Proposed Label for White Chocolate with Revised PDP

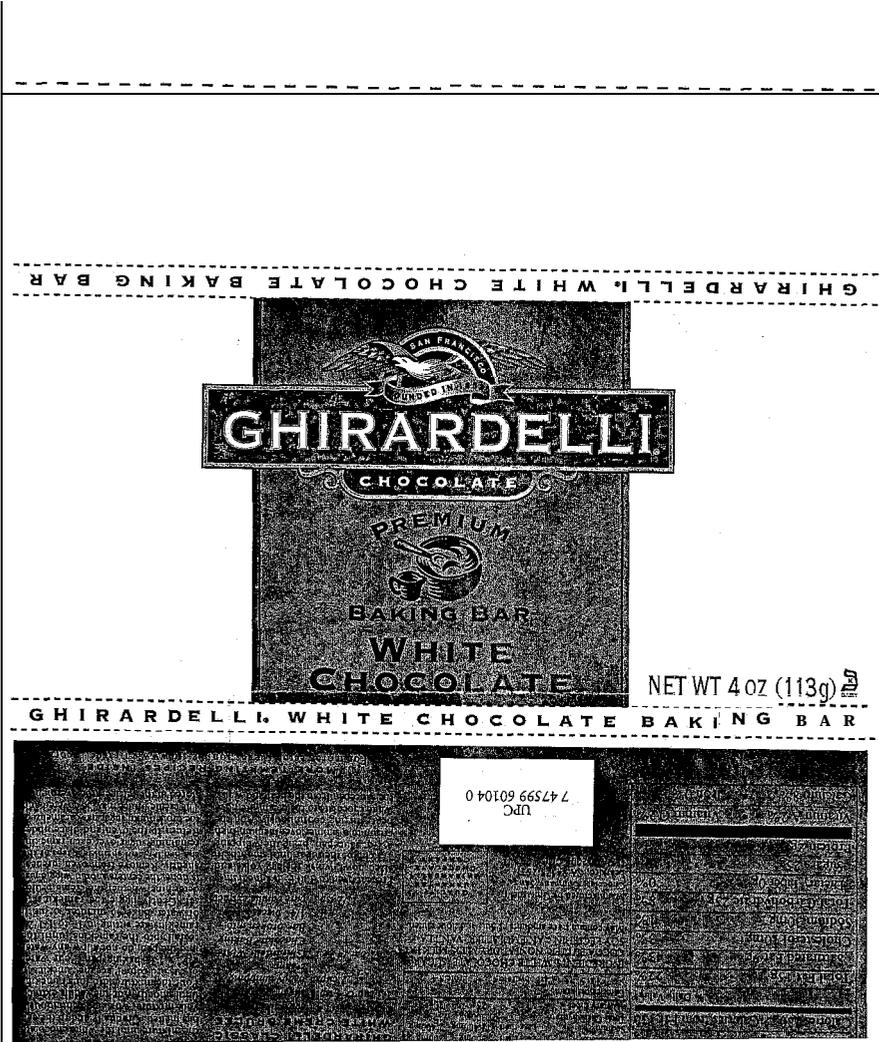
Dear Loretta:

Enclosed herewith please find a mockup revised print for Ghirardelli White Chocolate. If you will notice, the font sizes have been enlarged per your request. I have previously expressed the urgency needed for approval of this proposed label, so your immediate response would be appreciated. Please feel free to reach me at (510)346-3162.

Sincerely,

  
Lindsay Smith  
R&D Food Technologist

*New Label  
that was  
submitted*







GHIRARDELLI CHOCOLATE COMPANY

MAR 8 2001

March 2, 2001

Felicia Satchell  
Director, Division of Standards & Labeling  
Office of Nutritional Products, Labeling & Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

Attn: Loretta Carey

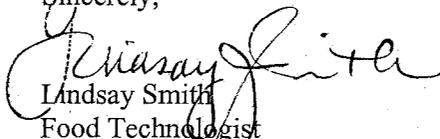
RE: Temporary Marketing Permit for White Chocolate

Dear Loretta:

If you will recall, in early January you notified me regarding the Ghirardelli White Chocolate Baking Bar label I had submitted to you along with the Temporary Marketing Permit for Participation in Extended Market Test of "White Chocolate" Docket No. 93P-03 10. At the time of your phone call, you brought to my attention that the Nutrition Facts panel located on the information panel of the proposed label was not within compliance of 21 CFR 101.9(d)(1)(iii). Since your phone call, Ghirardelli Chocolate Company has recognized your suggestion and taken all appropriate steps to correct the information panel. I am, once again, submitting the Temporary Marketing Permit, which was originally submitted on June, 22, 2000, as well as the revised proposed label for this product.

Please feel free to contact me at 510.346.3162 if you have any questions. I am confident that I have addressed your concerns and so I thank you for your assistance.

Sincerely,

  
Lindsay Smith  
Food Technologist  
Ghirardelli Chocolate Company

Encl.



GHIRARDELLI CHOCOLATE COMPANY

Rec'd  
11/21/00

November 14, 2000

Loretta Carey  
Food Standards Branch  
Office of Food Labeling (HFS-158)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

**Re:** Marketing Permit for Ghirardelli White Chocolate

Dear Loretta:

Thank you for your phone calls regarding the label for Ghirardelli White Chocolate. Enclosed herewith are the labels you were requesting. Should you find something missing or need additional information, please feel free to contact me at 510-346-3162.

Thank you for your assistance.

Sincerely,

Lindsay Smith  
Ghirardelli Chocolate Company  
Research & Development

Encl.



# WHITE CHOCOLATE

11/08/01

NET WEIGHT PRICE/LB.

0.63 lb \$3.99/lb

TOTAL PRICE

**\$2.51**



2 60186 00251 3

0319 0013

INGREDIENTS: Sugar, Cocoa Butter, Nonfat Milk Powder, Milk Fat, Soy Lecithin-An Emulsifier, Vanilla. May contain trace amounts of nuts and flour gluten.

MFD. By  
GHIRARDELLI CHOCOLATE CO.  
SAN LEANDRO, CA 94578-2631  
U.S.A. ©1999GCC  
GCC#0407



Nutrition Facts	Amount/Serving	%DV*	Amount/Serving	%DV*
	<b>Total Fat</b> 14g	<b>21%</b>	<b>Total Carb.</b> 23g	<b>8%</b>
<b>Sat Fat</b> 8g	<b>41%</b>	<b>Fiber</b> 0g	<b>0%</b>	
<b>Cholest.</b> 5mg	<b>2%</b>	<b>Sugars</b> 23g		
<b>Sodium</b> 30g	<b>1%</b>	<b>Protein</b> 2g		

Serv. Size 2" X 2" Piece (40g)  
Servings Varies  
**Calories** 200  
Fat Cal. 100

\*Percent Daily Values (DV) are based on a 2,000 calorie diet. Vitamin A 2% • Vitamin C 2% • Calcium 6% • Iron 0%

GHIRARDELLI® WHITE CHOCOLATE

PERFECTLY BLENDED FOR A RICH AND CREAMY TASTE



**GHIRARDELLI®**

**WHITE CHOCOLATE**  
FOR BAKING AND EATING

NET WT 4 oz (113g)

GHIRARDELLI® WHITE CHOCOLATE

For more than a century, Ghirardelli® premium baking products have been made according to a careful, old-world process. We add pure ingredients like cocoa butter and real vanilla, then blend for hours. The result is a confection so distinctively rich and creamy, it will make a difference in all your dessert creations.



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**INGREDIENTS:**  
WHITE CHOCOLATE (SUGAR, COCOA BUTTER, NONFAT DRY MILK, MILK FAT, SOY LECITHIN, AN EMULSIFIER, VANILLA).  
May contain trace amounts of nuts and flour gluten.

**CLASSIC WHITE CRÈME BRULÉE**  
4 large egg yolks at room temperature  
1/3 cup sugar  
2 cups whipping cream  
1 bar (4oz.) Ghirardelli White Chocolate, chopped in small pieces.  
1/2 tsp vanilla extract

Preheat oven to 300° F. In medium bowl, whisk egg yolks with sugar until smooth. In 2 quart saucepan, bring whipping cream to a simmer over medium high heat. Add white bar to simmering whipping cream. Turn off heat and whisk until white bar is melted. Add white mixture to egg yolk mixture one tablespoon at a time, whisking continuously to prevent eggs from scrambling. Whisk until smooth. Add vanilla. Pour into four ramekins

or custard cups. Place cups in 13" x 9" baking pan broiler pan. Add enough water so cups sit in 1 - 1 1/2" of water. Bake until set, about 45 minutes. Serve warm, at room temperature, or refrigerate overnight. For a delicious crunchy surface: Sprinkle the top of the crème brulée with 1 tsp of sugar and place under broiler until caramelized. Serves 4

**VALUABLE COUPON & MORE TEMPTING RECIPES INSIDE**

Each 4 oz. bar contains 8 sections (1/2 oz. e 2 sections equal 1 oz.

Manufactured by Ghirardelli Chocolate Co., San Leandro, CA 945782631, USA.  
© 2000 GCC

**Nutrition Facts**

Serving Size 3 sections (43g)  
Servings Per Container about 2.5  
Calories 230  
Calories From Fat 130

Amount/Serving	%Daily Value*	Amount/Serving	%Daily Value*
<b>Total Fat</b> 15g	<b>22%</b>	<b>Total Carbohydrate</b> 25g	<b>8%</b>
Saturated Fat 9g	43%	Dietary Fiber 0g	0%
Cholesterol 10mg	3%	Sugars 25g	
Sodium 30mg	1%	<b>Protein</b> 2g	
Vitamin A 2% • Vitamin C 2%		Calcium 8%	• Iron 0%

\* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Saturated Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g