



3007 '01 MAY -3 P2:46

APR 27 2001

Kathy Wilson  
Manager  
Formulations, Specifications & Regulatory Affairs  
Parmalat Canada  
Post Office Box 9052  
135 Otonabee Drive  
Kitchener, Ontario N2G 4J3

Re: 21 CFR 130.17(i) - Participation in Extended Market Test of "White Chocolate" under  
Docket No. 93P-0310

Dear Ms. Wilson:

This is to acknowledge your letters dated December 4, 2000, March 7, 2001, and March 23, 2001, and your fax dated March 1, 2001, notifying the Food and Drug Administration (FDA) of your acceptance of the invitation, set forth in the FEDERAL REGISTER of December 29, 1994 (59 FR 67302; Docket No. 93P-0310), to participate in the extended temporary market testing of "white chocolate" under the conditions published in the notice. Previously in a letter dated October 1, 1999, FDA granted a permit to Parmalat Canada to participate in the extended temporary market testing of white chocolate under Docket No. 93P-0310. That permit allowed for the market testing of a product named "Parmalat Bed and Breakfast White Chocolate Chunk and Macadamia Cookies." The agency is granting a further amendment to the permit of October 1, 1999. The amendment will allow for the market test of another product that contains white chocolate. The product will bear the name "Bed & Breakfast White Chocolate and Macadamia Cookies" and will be in sold in 0.78 ounce packages and 9.4 ounce (12 x 0.78 ounce) packages.

The test product "Bed & Breakfast White Chocolate and Macadamia Cookies" contains a component, identified as "white chocolate" that deviates from the U.S. standards of identity for certain chocolate products, i.e., 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). The white chocolate component differs from the standardized chocolate products in that: (1) it is prepared without the nonfat components of the ground cacao nibs, but contains the fat (cocoa butter) expressed from the ground cacao nibs; and (2) it may contain safe and suitable antioxidants. In all other respects, the white chocolate component would conform to the cacao product standards.

White chocolate, as defined under the extended permit, is the solid or semi-plastic food prepared by intimately mixing and grinding cocoa butter with one or more nutritive carbohydrate

93P-0310

ACK 2

Page 2 – Ms. Kathy Wilson

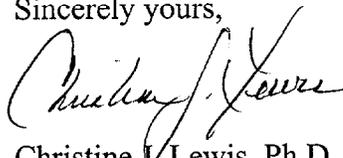
sweeteners and one or more of the optional dairy ingredients specified in part 163. It contains not less than 20 percent of cocoa butter, not less than 14 percent of total milk solids, not less than 3.5 percent of milkfat and not more than 55 percent of nutritive carbohydrate sweetener. It may also contain emulsifying agents, spices, natural and artificial flavorings and other seasonings, and antioxidants approved for food use. It contains no coloring material.

Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes, of 19,000 kilograms (42,000 pounds) of white chocolate for this test product annually. The test product will be manufactured for Mrs. Alison's of St. Louis, Missouri at Mrs. Alison's, 1 Cookie Cutter Lane, Highway 92 East, Plant City, Florida 33566, and distributed in New York, New Jersey, Connecticut, St. Louis Missouri, Cincinnati Ohio, and Chicago Illinois.

The draft labels that you submitted on March 23, 2001, for the test food are acceptable for the purpose of this market test. The finished labels must be submitted to the Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling, and Dietary Supplements, (HFS-820), before the product is shipped in interstate commerce. Each 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 "white chocolate" covered by this permit on the grounds that the food fails to comply with the standards of identity for certain chocolate 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,



Christine I. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition



**Bakery Division**

December 4, 2000

Chief of the Food Standards Branch  
Office of Food Labeling  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

Dear Sir or Madam,

Re: Parmalat Bed and Breakfast Soft and Chewy White Chocolate Chunk & Macadamia Cookies 8 oz and White Chocolate and Macadamia Cookies 12 x 0.78 oz

Enclosed please find draft labels of the above-named products for which we are requesting permission to conduct a test market.

This product will be manufactured at our plant, Mrs. Alison's, 1 Cookie Cutter Lane, Highway 92 East, Plant City, Florida 33566 (813)754-5565 for Mrs. Alison's of St. Louis, Missouri. The application is being submitted from the head office of the North American bakery division.

The cookies consist of white chocolate chunks and macadamia nuts in a buttery cookie base. Each cookie contains approximately 23% white chocolate. In accordance with CFR section 130.17.(c)(3), the white chocolate is in compliance with the proposed white chocolate standard published in the Federal Register/Vol.62, No. 46, Monday March 10, 1997, Docket Nos. 86P-0297 and 93P-0091. A copy of the product specification has been enclosed for your reference.

We plan to distribute about 50,000 cases of 6 x 8 oz soft and chewy cookies and 50,000 cases of 12 x 0.78 oz of the regular variety. The products will be sold in New York, New Jersey, Connecticut, St. Louis Missouri, Cincinnati Ohio and Chicago Illinois.

At 23% of the finished product, we will be distributing about 42,000 lb (19,000 kg) of white chocolate.

We appreciate your early attention to this matter. Please contact us if you require any further information.

.../2

10013  
C.H.M.  
0302  
C.H.M.  
→ to Beatha 12/11/00  
DEC - 5 2000  
Beatha Stanley

Kind regards,

*Kathy Wilson*

Kathy Wilson  
Manager Formulations, Specifications & Regulatory Affairs

Encl.

Cc: Eduardo Schur  
Aubrey Williams  
Rose Lauer

# BARRY CALLEBAUT

U.S.A.

## 70-106 Ultimate White Chunks

April 15, 1999

Total Weight: 100.00 g (3.53 oz-wt.)  
 Serving Size: 100.00 g (3.53 oz-wt.)  
 Serves: 1.00

Per Serving

Nutrient	Amount Per 100g	Amount Per Serving
<b>Basic Components</b>		
Calories	523.16	523.16
Protein	6.86 g	6.86 g
Carbohydrates	64.23 g	64.23 g
Dietary Fiber	0 g	0 g
Soluble Fiber	0 g	0 g
InSoluble Fiber	0 g	0 g
Sugar - Total	64.21 g	64.21 g
Other Carbs	0 g	0 g
Fat - Total	27.63 g	27.63 g
Saturated Fat	16.42 g	16.42 g
Mono Fat	9.02 g	9.02 g
Poly Fat	0.76 g	0.76 g
Cholesterol	9.10 mg	9.10 mg
Water	0.73 g	0.73 g
Ash	0.49 g	0.49 g
<b>Vitamins</b>		
Vitamin A IU	104.44 IU	104.44 IU
Thiamin-B1	0.09 mg	0.09 mg
Riboflavin-B2	0.39 mg	0.39 mg
Niacin-B3	0.19 mg	0.19 mg
Vitamin-B6	0.09 mg	0.09 mg
Vitamin-B12	0.75 mcg	0.75 mcg
Vitamin C	3.21 mg	3.21 mg
Vitamin D IU	-- IU	-- IU
Vitamin E IU	0.53 IU	0.53 IU
Folate	8.57 mcg	8.57 mcg
Pantothenic Acid	0.53 mg	0.53 mg
<b>Minerals</b>		
Calcium	248.70 mg	248.70 mg
Copper	-- mg	-- mg
Iron	0.11 mg	0.11 mg
Magnesium	27.99 mg	27.99 mg
Manganese	0 mg	0 mg
Phosphorus	198.49 mg	198.49 mg
Potassium	308.61 mg	308.61 mg
Selenium	-- mcg	-- mcg
Sodium	103.36 mg	103.36 mg
Zinc	0.74 mg	0.74 mg
<b>Other</b>		
Caffeine	0 mg	0 mg
Sugar Alcohol	-- g	-- g

Barry Callebaut U.S.A. Inc.  
 100 Industrial Park Road - St. Albans, VT 05478-1876  
 Tel.: (802) 524-0711 Fax: (802) 524-5148

FROM: BARRY CALLEBAUT CANADA TO : 1314 429 2111 1999, 04-15 09:58PM #431 P.04/04



U.S.A.

### CERTIFICATE OF ANALYSIS

Item No: 70106 ULTIMATE WHITE CHUNKS 600 CT  
 Product Lot No: 20046  
 Date shipped: 03/26/99  
 B/L no: 0074713

#### Analytical Results

Description	Units	Results
Salmonella spp.	(737.5g)	NEGATIVE
Total Plate Count	(CFU/g)	< 5,000
S. aureus	(CFU/g)	< 10
Yeasts	(CFU/g)	< 50
Molds	(CFU/g)	< 50
Total Coliforms	(MPN/g)	< 10.0
E. coli	(MPN/g)	< 3.0
Fat Content	(%)	27.2
Moisture Content	(%)	0.73
Count per Pound	(pieces)	593

Analysis approved by: Manon Proulx  
 Quality Control Dir.

As this document is verified, approved and generated electronically, it is not signed.

70106

70-106

SUGAR, COCOA BUTTER, WHOLE MILK POWDER, SKIM MILK POWDER, BUTTERFAT, SOYA LECITHIN (ADDED AS AN EMULSIFIER), VANILLA EXTRACT.

Att: David Burns  
"Mrs Allisau"



**Bakery Division**

**FAX MESSAGE**

**DATE:** March 1, 2001

**TO:** Ritu Nalubola  
FDA

**PHONE:** (202) 205-3124  
**FAX:** (202) 205-5295

**FROM:** Kathy Wilson  
Mgr – Regulatory Affairs

**PHONE:** (519) 893-6400 x 250  
**FAX:** (519) 893-9223

**RE:** **Bleached Flour Ingredient Declaration**

**CC:**

**Number of Pages Including Cover Page:** 5

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**MESSAGE:**

Dear Ritu,

Attached please find excerpts from "Food Labeling – Requirements for FDA Regulated Products" written by American Institute of Baking in cooperation with FDA.

I have included the part advising that "bleached flour" may be declared as such without having to list the bleaching agent.

I hope this addresses your concern regarding this declaration and will be back to you shortly on the other issues you raised.

Regards,

*Kathy Wilson*

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**COLONIAL COOKIES, A DIV. OF PARMALAT CANADA BAKERY DIVISION**

P.O. Box 9052, 135 Otonabee Drive, Kitchener ON N2G 4J3

Phone: (519) 893-6400 Fax: (519) 893-9223

# **Food Labeling – Requirements for FDA Regulated Products**

written by:  
**James L. Vetter, Ph.D.**  
**Consultant**  
**Technical Assistance Services**

published by:  
**American Institute of Baking**  
**Manhattan, Kansas**

In cooperation with the  
**U.S. Department of Health and Human Services**  
**Food and Drug Administration**  
**Washington, D.C.**

Issued 3/99

# Preface

## **A message from the Food and Drug Administration:**

The legal requirements for food labeling can often be complex and difficult to understand. Their purpose is to insure that foods are properly labeled so that the consumer may be able to make informed buying decisions. Consistent with its regulatory philosophy which includes prevention through assistance as a complement to legal action, the Food and Drug Administration is pleased to cooperate with the American Institute of Baking in the development of this most worthwhile discussion of "Food Labeling - Requirements for FDA Regulated Products." It should be a great help in assuring compliance with food labeling requirements.

## **A message from the author:**

No book can be the result of the efforts of a single individual. Although I take responsibility for the final contents of the book and any errors that may be found, I greatly appreciate and acknowledge the efforts of others who helped in so many ways to take this project from the conceptual phase to a finished product.

John Tisler and his staff in the Industry Activities Section of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration have been most cooperative, timely, and helpful in their review of the manuscript. They have proved to me that the FDA is not always an adversarial agency!

My thanks to Dr. William J. Hoover, President of AIB, for his encouragement and approval to undertake this project.

**Animal or Vegetable.** If the products which may be used include both animal and vegetable shortenings, the declaration is somewhat more complex:

animal or vegetable oil shortening (may contain one or more of the following: lard, cottonseed oil, palm oil, soybean oil)

or

animal or vegetable oil shortening (lard, cottonseed oil, palm oil, or soybean oil)

or

animal or vegetable oil shortening (lard, cottonseed oil, palm oil, and/or soybean oil)

**"Or" or "And/or".** The term "or" should be used when only one of the listed products is used at any one time. The term "and/or" should be used when two or more of the products listed may be used at any one time.

## Wheat Flour

### Common or Usual Names

Regulations (21CFR 137) specify the common or usual names for various types of wheat flour. These names are listed in Table V-3.

**Definition of "Flour".** When the term "flour" is used alone, it refers to white flour from wheat. Flour from any other source must include the name of the source such as "rye flour", "corn flour", "soy flour", etc.

**Standardized Flours.** There are a number of standardized flour products in which a number of ingredients may be added. These include bromated flour, enriched flour and self-rising flour. The first ingredient listed in the parenthetical listing of ingredients for these products should be "flour", "unbleached flour", or "bleached flour" followed by any other optional ingredient added in order of predominance. For example:

Table V-3 Common or Usual Names for Wheat Flours	
Product	Common or Usual Name
White Flour	flour or white flour or wheat flour or plain flour
Durum Flour	durum flour
Whole Wheat Flour	whole wheat flour or graham flour or entire wheat flour
Whole Durum Wheat Flour	whole durum wheat flour

enriched flour (flour, niacin, ferrous sulfate, thiamine, and riboflavin)

OR

enriched bleached flour (bleached flour, niacin, ferrous sulfate, thiamine, and riboflavin)

If the flour is bleached, it should be declared as "bleached flour"; it is not necessary to declare the bleaching agent. If the flour is unbleached, it may be declared either as "unbleached flour" or "flour". The terms white flour, wheat flour, or plain flour may be used in place of just flour.



**parmalat**  
CANADA

**Bakery Division**

March 7, 2001

Ms. Ritu Nalubola  
Office of Food Labeling  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

Dear Ritu,

Re: Parmalat Bed and Breakfast White Chocolate and Macadamia Cookies 12 x 0.78 oz

Further to our telecon of March 1, 2001 we have made modifications to the above labels as follows:

Individual Package

1. The net quantity has been separated from the Kosher symbol.
2. The photo of the cookie has not been enlarged on this package; therefore we have not included a statement such as "Enlarged to show texture".
3. The actual space available to bear labeling on this package is about 23 square inches given that about 1 inch is taken off each side of the package for seals; therefore we are not able to use a different Nutrition Facts format.
4. We want to keep this package consistent with the rest of the line; therefore we will be leaving "Recipe includes..." prior to the ingredient list.
5. I believe the issue of declaring "bleached wheat flour" has been addressed.

Outer Vend Tray 12 x 0.78 oz

1. The net quantity has been separated from the Kosher symbol.
2. The photo of the cookie has been enlarged on this package; therefore we have included the statement "Enlarged to show texture" on the main panel.
3. We want to keep this package consistent with the rest of the line; therefore we will be leaving "Recipe includes..." prior to the ingredient list.
4. I believe the issue of declaring "bleached wheat flour" has been addressed.

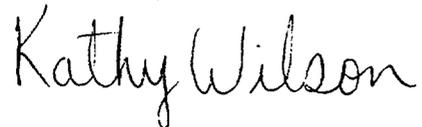
Please note plans to launch the Soft and Chewy White Chocolate & Macadamia Cookie 8 oz have been put on hold for the time-being. We will contact FDA again in the event this project is re-activated.

We trust everything is now in order; however should you notice anything else, please notify us immediately as we are in the process of printing packaging.

.../2

Many thanks for your assistance in this matter.

Best regards,

A handwritten signature in cursive script that reads "Kathy Wilson". The letters are fluid and connected, with a prominent loop on the 'y'.

Kathy Wilson  
Manager Formulations, Specifications & Regulatory Affairs

Encl.

Cc: Aubrey Williams



**parmalat**  
CANADA

**Bakery Division**

MAR 23 2001

March 23, 2001

Ms. Ritu Nalubola  
Office of Food Labeling  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

Dear Ritu,

Re: Parmalat Bed and Breakfast White Chocolate and Macadamia Cookies 12 x 0.78 oz

Further to our recent telecon we have amended "recipe includes" to "ingredients include" on the above named product labels – both on the outer vend tray and on the individual wrapper.

We trust that everything is now in order for us to receive test market approval.

Best regards,

*Kathy Wilson*

Kathy Wilson  
Manager Formulations, Specifications & Regulatory Affairs

Encl.

Cc: Aubrey Williams

8.625"

CLEAR FOR CRIMP SEAL

**Ingredients include:**  
 Bleached Wheat Flour, White Chocolate Chunks (Sugar, Cocoa Butter, Milk, Skim Milk, Butterfat, Soybean Lecithin, Natural Flavor), Sugar, Vegetable Oil Shortening (Partially Hydrogenated Soybean and Cottonseed Oil with Citric Acid as a Preservative), Butter, Macadamia Nuts, Contains 2% or Less of: Whey, Natural and Artificial Flavor, Eggs, Corn Syrup, Brown Sugar, Leavening (Baking Soda, Ammonium Bicarbonate), Salt.

**NET WT**  
 .78 OZ (22 g)

**EXP**  
 0 72413 00871 3

**Ingredients include:**  
 Bleached Wheat Flour, White Chocolate Chunks (Sugar, Cocoa Butter, Milk, Skim Milk, Butterfat, Soybean Lecithin, Natural Flavor), Sugar, Vegetable Oil Shortening (Partially Hydrogenated Soybean and Cottonseed Oil with Citric Acid as a Preservative), Butter, Macadamia Nuts, Contains 2% or Less of: Whey, Natural and Artificial Flavor, Eggs, Corn Syrup, Brown Sugar, Leavening (Baking Soda, Ammonium Bicarbonate), Salt.

**Nutrition Facts**  
 Serv size 1 cookie (22g), Amount Per Serving:  
 Calories 130, Fat Cal. 70, Total Fat 7g (11% DV), Sat. Fat 2.5g (4% DV), Cholesterol 10mg (3% DV), Sodium 45mg (2% DV), Total Carb. 15g (5% DV), Fiber 0g (0% DV), Sugars 8g, Protein 1g, Vitamin A (0% DV), Vitamin C (0% DV), Calcium (2% DV), Iron (0% DV), Percent Daily Values are based on a 2,000 calorie diet.

MANUFACTURED IN A FACILITY THAT PROCESSES NUT PRODUCTS  
 Manufactured by BF USB Inc.  
 A subsidiary of  
 Parmalat Daily & Bakery Inc.  
 1780 Burns Avenue  
 St. Louis, MO 63132

1" CLEAR

5.25"

WEB DIRECTION

1" CLEAR

Please note that shadow should look like this when printed

CLIENT'S SIGN-OFF

CLIENT'S SIGN-OFF

LOGOS<sup>®</sup>

Comments:

81 The East Mall Suite 201 Toronto Ontario M8Z 5W3  
 (T) 416 259 7834 (F) 416 259 4053

March 21 / 01