



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

AUG 29 2001

1383 '01 AUG 31 A9:50

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

Dear Ms. Wilson:

This is to acknowledge your letter of June 12, 2001, 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 Hersey Foods Corporation (59 FR 67302, December 29, 1994). Previously in two letters dated October 1, 1999 and April 27, 2001, FDA granted permits to Parmalat Canada to participate in the extended temporary market testing of white chocolate under Docket No. 93P-0310. Those permits allowed for the market testing of products named "Parmalat Bed and Breakfast White Chocolate Chunk and Macadamia Cookies" and "Bed & Breakfast White Chocolate and Macademia Cookies." The agency is granting a further amendment to the permits of October 1, 1999 and April 27, 2001. The amendment will allow for the market test of another product that contains white chocolate. The product will bear the name "Absolutely Divine White Chocolate Chip Macadamia Cookies" and will be sold in 12 ounce packages.

The test product "Absolutely Divine White Chocolate Chip 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 of the product differs from 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.

Relying on the representations made in your application, we are hereby granting permission to make interstate shipments, for market testing purposes of 108,000 pounds (49,000 kg) of new test product. The product will be manufactured at Colonial Cookies, 135 Otonabee Drive, Kitchener, ON N2G 4J3 and will be distributed in Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, Pennsylvania, New Jersey, Delaware, Michigan, Illinois, Indiana, Tennessee, Maryland, Virginia, North Carolina, South Carolina, Georgia, Alabama, and Nevada.

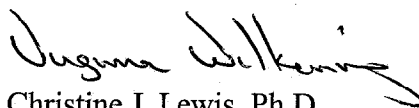
93P-0310

LET 98/ANS

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-822), 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 “Absolutely Divine White Chocolate Chip Macadamia Cookies” 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,



for Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Page 3 – Ms. Kathy Wilson

cc:

GCF-1

HFA-224 (yellow box copy)

HFA-305 (w/copy incoming)

HFS-1

HFS-4

HFS-22

HFS-636 (Wade)

HFS-800 (Lewis, Hawkins-Minor)

HFS-820

HFS-822 (June, Carey)

R/D:HFS-822:LCarey:8/20/01:202-205-4168

Revised:HFS-822:LCarey:8/22/01

Init:HFS-822:GJune:8/22/01

F/T:bls:8-24-01

DOC: found on “p” drive via:

DSL\data/Conventional Foods Team/TMP/Confidential/76458 Wilson

2001-106

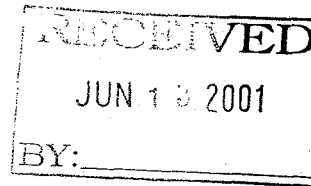
Satchell

76458



parmalat
CANADA

Bakery Division



June 12, 2001

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: CVS Absolutely White Chocolate & Macadamia Cookies 12 oz (340g)

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

This product will be manufactured at our plant, Colonial Cookies, 135 Otonabee Drive, Kitchener ON N2G 4J3 (800) 265-6508 for CVS Pharmacy, Inc. of Woonsocket, RI.

The cookies consist of white chocolate chips and macadamia nuts in a buttery cookie base. Each cookie contains approximately 24% 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 annually of 12 x 12 oz of this product. The products will be sold in Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, Pennsylvania, New Jersey, Delaware, Michigan, Illinois, Indiana, Tennessee, Maryland, Virginia, North Carolina, South Carolina, Georgia, Alabama and Nevada.

At 24% of the finished product, we will be distributing about 108,000 lb (49,000 kg) of white chocolate.

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

.../2

Kind regards,

Kathy Wilson

Kathy Wilson
Manager Formulations, Specifications & Regulatory Affairs

Encl.

Cc: Bruce Gingrich
Aubrey Williams
Rose Lauer

CANADA

PRODUCT SPECIFICATION (Tentative)

This tentative specification is currently under review. Therefore its contents is subject to change.

Description : Ultimate White Chocolate Chips - 2M
Weight / unit : 50 lbs
Units / pallet : 40 cases
Kosher Certification : Ⓚ D

Item No: 70-084
Style : Chips
Form: N/A
Size: 2,000 ct/lb

Ingredients: Sugar, cocoa butter, whole milk powder, skim milk powder, butterfat, soya lecithin (added as an emulsifier), vanilla extract

Chemistry and Physical Characteristics :

	Criteria	Method
Size	2,000 ± 100 ct/lb	MML 1041 (Weight Of 100 Pieces)
Fat Content	27.8 ± 1.0%	MML 1001 (NMR)
Moisture	1.0% Max	MML 1011 (Near Infra-Red)
Particle Size	85% < 29µ	MML 1006 (Laser Diffraction)
Viscosity	N/A	

Microbiology :

	n	c	m	M	Method
Total plate count	5	2	1,000	5,000	MML 1080
Yeasts	5	2	10	50	MML 1082
Molds	5	2	10	50	MML 1082
Staph. Aureus (coag+)	5	0	0	10	MML 1081
Coliforms	5	2	0	10	MML 1083
E. Coli	5	0	0	0	MML 1083
Salmonella	15	0	0	0	MML 1085

Packaging : Corrugated cardboard carton with a polyethylene liner

Shipping : Cases are stacked and stretch-wrapped on a non-returnable wooden pallet

Storage : Product must be shipped and stored at temperatures not exceeding 68°F/20°C

CONTROLLED DOCUMENT
Vice President North America

98-09-24

Barry Callebaut Canada Inc.
B.P./P.O. Box 398 - 2950 rue Nelson street, Saint-Hyacinthe (Quebec) Canada J2S 1Y7
Tél.: (450) 774-9131- Télécopieur: (450) 774-8335 / www.barry-callebaut.com

Rev: 00

ABSOLUTELY
DIVINE

*White Chocolate Chip
Macadamia COOKIES*

*The addition of rich,
creamy white chocolate
provides a twist to the
traditional Macadamia
Nut Cookie. A sweet,
buttery recipe that makes
a cookie with an old-
fashioned homemade taste.*

*I'm proud to put our
name on this product. It
represents the quality and
value you've come to expect
from CVS. I know you'll
enjoy the great taste.
As always, it carries our
money back guarantee.*

Jim Lepore CEO



PREMIUM
QUALITY
GREAT
VALUE

ABSOLUTELY
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*White Chocolate Chip
Macadamia COOKIES*



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COOKIES



ABSOLUTELY DIVINE

PREMIUM
QUALITY
GREAT
VALUE

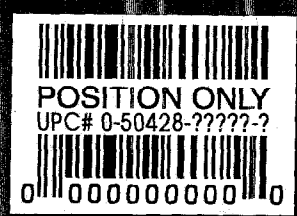
*White Chocolate Chip
Macadamia COOKIES*



SEPARATOR PLEASE ADD
COOKIE & NUT SHADOWS
WHERE NECESSARY AS
PER TRANSPARENCY
SUPPLIED

ts
180
ure*
19%
-9%
%
1/2
1/6

NET WT 12 OZ (340g)




FOLDER NAME: M8033 CVS Cookies		FILE NAME: P8033 Macadamia Cookies F/A	
Process Cyan (Screen) Process Magenta (Screen) Process Yellow (Screen) Process Black (Screen) Pantone 872 (Line)	Line Black Pantone 3005 (Screen) Pantone 485 (Target match using Process) Varnish (No Ink) Die Lines (No Print)	Fonts <ul style="list-style-type: none"> • Avant Garde Cond Med, Cond Bold, Cond Book, Cond Demi • Centaur Bold / Bold Italic • Helvetica / Bold / Med • Helvetica Cond Med / Cond Bold • Helvetica 95 Black • Frutiger Roman / Bold • Futura Bold • Trajan Bold • Shelley Andante Script 	Notes <ul style="list-style-type: none"> • Art prepared with Adobe Illustrator v8 0.1 • Artwork prepared at size as for Roto printing • Apply appropriate trapping. Set elements to knock out and overprint as necessary. • Adjust vignettes as necessary. • See previous printed packages for printing "Line Black" • Adjust blend as required. • UPC - 100% • Scan from transparencies supplied
Important: Although every effort is made to produce the finest possible product, errors can occur. Please check this proof/PDF file carefully.		Separator: If electronic art does not match this print - do not proceed! This laser proof for colour break only and may not accurately reflect actual product shown for reference only - do not print.	



SHOWN LARGER
THAN ACTUAL SIZE

NET WT 12 OZ (340g)

3 June 11, 2001

 watt international

Approved Designer _____
Approved Prod. Dir. *[Signature]*
Approved Proj. Mgr. _____
Approved Proofread _____

Client Approved _____

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USE OF EITHER A "®"
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TO ACCOMPANY THE
CVS LOGO