



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

MAR 16 2001

Earl Weak
R & D Director
Mother's Cake & Cookie Co.
810-81st Avenue
Oakland, California 94621-2583

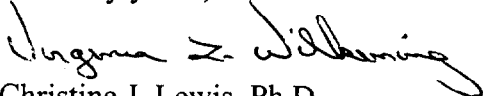
Re: 21 CFR 130.17(i) – Participation in Extended Temporary Marketing Test of
“White Chocolate” under Docket No. 93P-0310

Dear Mr. Weak:

This is in response to your label submission for the product, “Ghirardelli Chocolate White Chocolate Chip Macadamia Premium Cookies.” On February 14, 2001, the Food and Drug Administration (FDA) granted a temporary marketing permit for the product, “Ghirardelli Chocolate White Chocolate Chip Macadamia Premium Cookies.” In that letter, we failed to point out that the declaration of required information appearing on the information panel (including nutritional information, ingredient statement, and name and place of manufacturer) must appear in one place without other intervening material, in accordance with Title 21 Code of Federal Regulations Section 101.2(e). Two intervening statements appear between the ingredient statement and the name and place of manufacturer declared on the information panel of your final label. While FDA has previously used enforcement discretion regarding the placement of allergen information statements immediately beneath the ingredient statement, we do object to the placement of the toll free number between the ingredient statement and the name and place of manufacturer. Therefore, the toll free number must be moved from its current position. An appropriate place for this statement could be at the end of, and separated from, the required information appearing on the information panel. The final label that you submitted may be used for marketing test of your product until your current label inventory is exhausted. At the next printing, however, the labels must be revised to reflect the appearance of required information on the information panel without other intervening material. For our records, please submit copies of the finished labels when they are revised.

If you have further questions, please do not hesitate to contact us.

Sincerely yours,


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

93P-0310

LET94

5417 01
MAR 19 13:57



FEB 21 2001

February 21, 2001

Dr. Christine Lewis
Director Office of Nutrition Products,
Labeling and Dietary Supplements
HFS - 820
Food & Drug Administration
200 - C Street, SW
Washington DC 20204

Dear Dr. Lewis:

Please find enclosed two samples of the final label for the White Chocolate Chip Macadamia Premium Cookies. This action is in compliance to your letter of February 14, 2001 requesting a sample of the final label.

Thank you for your assistance with this project.

Sincerely,

Earl Weak
R & D Director

Enclosures

2000-27

74106



January 17, 2001

Dear Ms. Satchell:

Here is the corrected label for the White Chocolate Macadamia Cookies. This should take care of the requirements for the marketing permit of a white chocolate item.

Thank you for your assistance with this project.

Sincerely

A handwritten signature in black ink that reads "Earl Weak". The signature is written in a cursive style with a large, sweeping "E" and "W".

Earl Weak
R&D Director

GHIRARDELLI

CHOCOLATE

NEW
GHIRARDELLI

CHOCOLATE

FRESHLY BAKED COOKIES

White Chocolate
Chip Macadamia

COOKIES
ENLARGED
TO SHOW
TEXTURE

NET WT. 8.25 OZ. (234g)

Cookies

Larger Than

GHIRARDELLI



EW

GHIRARDELLI

CHOCOLATE

*White Chocolate
Chip Macadamia*

NET WT. 8.25 OZ. (234g)

Cookie

Larger Than



GHIRARDELLI





White Chocolate Chip Macadamia

GHIRARDELLI
CHOCOLATE



GHIRARDELLI
CHOCOLATE

PREMIUM COOKIES

White Chocolate
Chip Macadamia

EM

EM



November 7, 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, Mother's Cake and Cookie Co. 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 Mother's Cake & Cookie Company, 810 – 81st Avenue, Oakland CA 94621.
2. The cookie containing white chocolate will be manufactured at Mother's Cake & Cookie Company, 810 – 81st Avenue, Oakland CA 94621.
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 three (3) state test market and then all fifty (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.

Mother's Cake & Cookie Company understands 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 thirty (30) days after termination of such proposal.

Sincerely,



Earl Weak
R & D Director

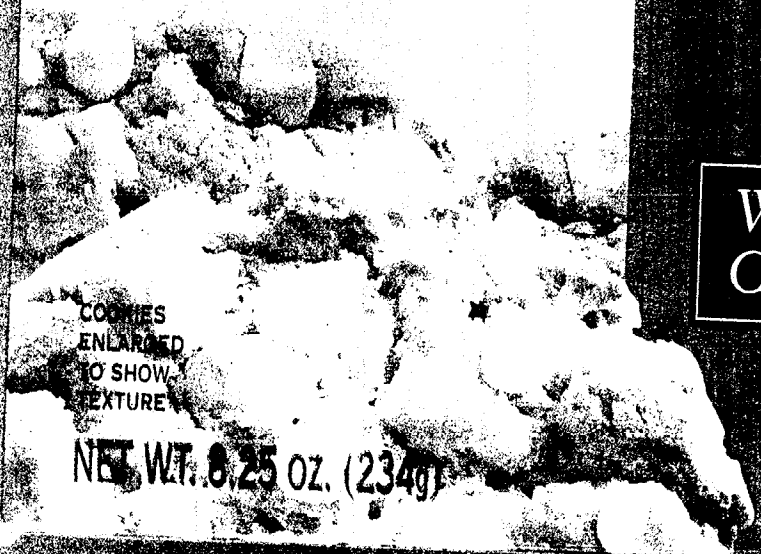
NEW



GHIRARDELLI

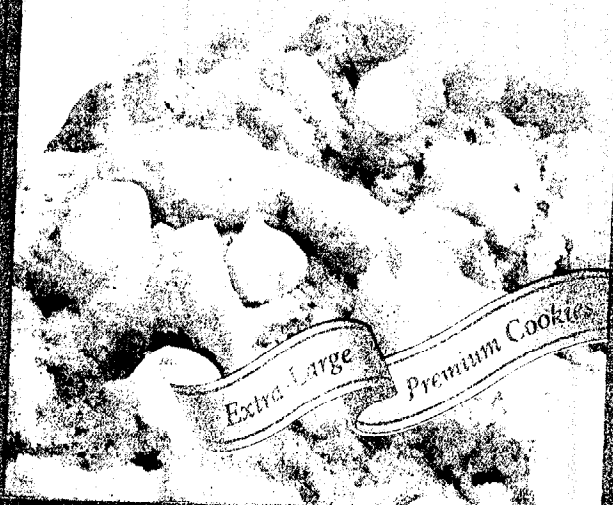
CHOCOLATE

White Chocolate Chip Macadamia



COOKIES
ENLARGED
TO SHOW
TEXTURE

NET WT. 8.25 OZ. (234g)



Extra Large
Premium Cookies



GHIRARDELLI

Superior Taste

GHIRARDELLI

CHOCOLATE

NEW

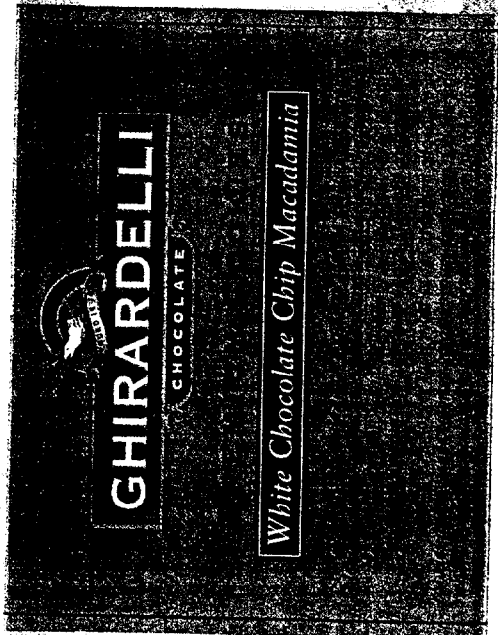
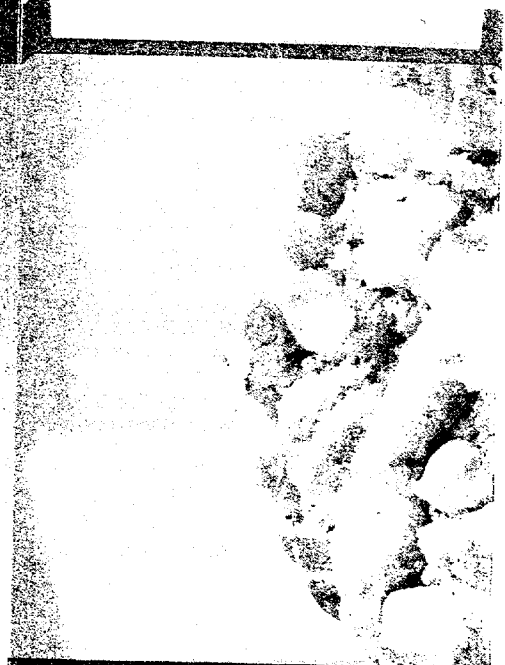


GHIRARDELLI

CHOCOLATE

PREMIUM COOKIES

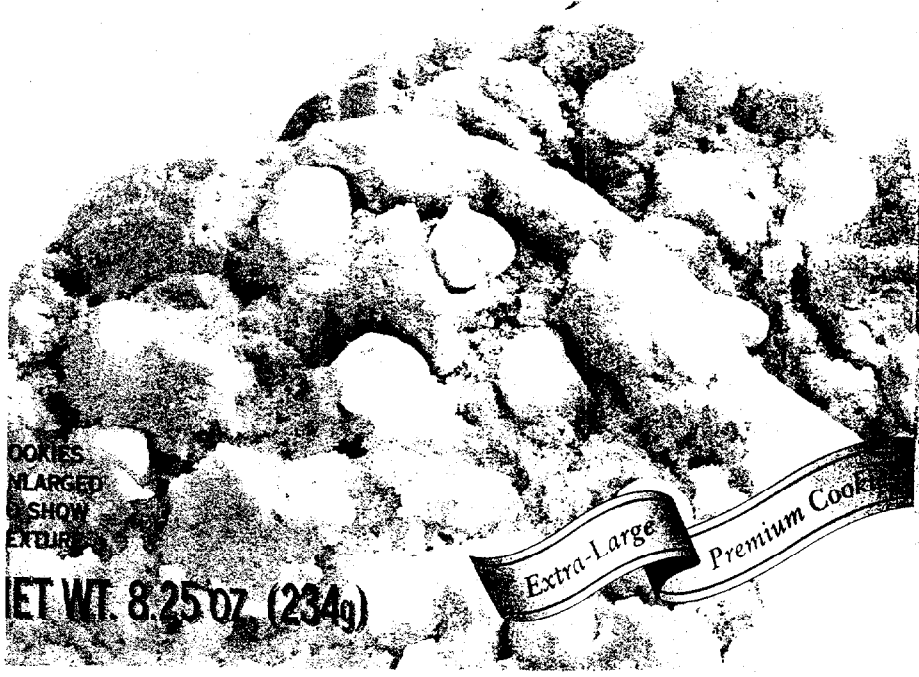
*White Chocolate
Chip Macadamia*



GHIRARDELLI

CHOCOLATE

White Chocolate Chip Macadamia



COOKIES
ENLARGED
FOR SHOW
EXHIBIT

NET WT. 8.25 OZ. (234g)

*Extra-Large
Premium Cookies*





FEB 14 2001

Earl Weak
R & D Director
Mother's Cake & Cookie Co.
810-81st Avenue
Oakland, California 94621-2583

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

Dear Mr. Weak:

This is to acknowledge your letter of November 7, 2000, 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 November 13, 1996, FDA granted a permit to Mother's Cake and Cookie Company 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 "Double Chips Chocolate Chip Cookies." The agency is granting a further amendment to the permit of November 13, 1996. The amendment will allow for the market test of another product that contains white chocolate. The product will bear the name "Ghirardelli Chocolate White Chocolate Chip Macadamia Premium Cookies."

The test product "Ghirardelli Chocolate White Chocolate Chip Macadamia Premium Cookies" contains a component, identified as "white chocolate" that deviates from the United States 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 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

Page 2 – Mr. Earl Weak

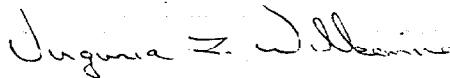
carbohydrate sweetener. It may also contain emulsifying agents, spices, natural and artificial flavorings and other seasonings, and antioxidants approved for food use. It contains no coloring material.

Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes, of 120,365 pounds of the test product annually. The test product will be manufactured at Mother's Cake & Cookie Company, 810-81st Avenue, Oakland, California 94621, and distributed nationwide.

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 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,



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

Page 3 – Mr. Earl Weak

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, Wilkening, Thomas, Hawkins-Minor)

HFS-820

HFS-822 (June, Nalubola)

R/D:HFS-822:RNalubola:1/31/01:202-205-3124

Revised:RNalubola:2/06/01

Init:HFS-822:GJune:2/07/01

Init:HFS-820:FSatchell:2/9/01

F/T:bls:2/9/01

DOC: found on “p” drive via:

DSL Rdata/Conventional Foods Team/Temporary Marketing Permit/74106 Weak



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

MAR 16 2001

Earl Weak
R & D Director
Mother's Cake & Cookie Co.
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Oakland, California 94621-2583

Re: 21 CFR 130.17(i) – Participation in Extended Temporary Marketing Test of
“White Chocolate” under Docket No. 93P-0310

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If you have further questions, please do not hesitate to contact us.

Sincerely yours,

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

93P-0310

LET94

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