DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

MAR 9 2001

0359 '01 MAR 14 P3:00

Paula M. Nothofer
Regulatory Compliance-Labeling
Kraft Foods, Inc.
555 South Broadway
Tarrytown, New York 10591

Dear Ms. Nothofer:

This is to acknowledge your letter of January 2, 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 a letter dated September 25, 1995, FDA granted a permit to Kraft Foods 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 "Premium White Chocolate Baking Squares." The permit was amended on August 23, 1996, to provide for an additional total of 30,391 kilograms (67,000 pounds) of other white chocolate products. The agency is granting a further amendment to the permit of September 25, 1995. The amendment will allow for the market test of another product that contains white chocolate. The product will bear the name "Baker's Brand Premium White Chocolate Chunks."

The white chocolate component of the product differs from the 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 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 88,000 pounds (39,909 kg) of new test product. The product will be manufactured at Barry Callebaut USA, Inc., 400 Industrial Park Road, St. Albans, VT 05478-1875 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 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 "Baker's Brand Premium White Chocolate Chunks" covered by this

93P-0310

LET 93

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

ANDREA M. BRUCE
ATTORNEY AT LAW

DIRECT DIAL
(202) 637-6456

HOGAN & HARTSON L.L.P.

555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004
TEL. (202) 637-5600
FAX (202) 637-5910

AMBRUCE@HHLAW.COM

January 2, 2001

Loretta A. Carey
Food Standards Branch (HFS-158)
Division of Programs and Enforcement Policy
Office of Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Docket Numbers 93P-0310, 94P-0157
21 CFR 130.17(i)-Notice of Participation In
Extended Market Test Of White Chocolate

Dear Ms. Carey:

On July 20, 1995, we notified the Food and Drug Administration that Kraft Foods, Inc. accepts the agency's invitation to participate in the extended market test of white chocolate, announced in the Federal Register on December 29, 1994; 59 Fed. Reg. 67302 (Docket No. 93P-0310). At this time, we are notifying the agency that Kraft intends to include an additional product, Baker's Brand Premium White Chocolate Chunks, in the ongoing market test.

Docket No. 94-P-0157 (July 1, 1994; 59 Fed. Reg. 33976), the docket number for the temporary permit to market white chocolate originally issued to Kraft in 1994, contains relevant procedural history as well as a description of the proposed test product. The product description has not changed, but is repeated here for convenient reference.

1. The name of the applicant is Kraft Foods, Inc. The headquarters address is Three Lakes Drive, Northfield, IL 60091.

2. Kraft Foods is regularly engaged in the business of manufacturing and marketing cacao products.

3. The "white chocolate" we propose to market test differs from the existing standards of identity for chocolate products, e.g., chocolate liquor (21 CFR 163.111), sweet chocolate (21 CFR 63.123), milk chocolate (21 CFR 163.130), buttermilk chocolate

(21 CFR 163.135), skim milk chocolate (21 CFR 163.140), and mixed dairy product chocolates (21 CFR 163.145).

4. The proposed difference from the existing standards of identity recognizes that the product commonly known among consumers and in other countries as "white chocolate" is made with cocoa butter. The cocoa butter is produced by filtering ground cocoa nibs to remove the dark cocoa solids.

   The composition of the "white chocolate" we propose to market test is consistent with the standard of identity for "white chocolate" proposed in citizen's petitions filed by Hershey Foods Corporation and the Chocolate Manufacturers Association (Docket numbers 86-P0297/CP2 and 86P-0297/CP3).

   More specifically, the "white chocolate" we propose to market test 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 part 163. The product contains not less than 20 percent cocoa butter, not less than 14 percent total milk solids, not less than 3.5 percent milk fat, and not more than 55 percent nutritive carbohydrate sweetener. It contains no coloring material, but may contain emulsifying agents, spices, natural and artificial flavoring and other seasonings, and antioxidants approved for food use.

5. The food "white chocolate" is just as wholesome and non-deleterious as the cacao products that are subject to existing standards of identity. No novel ingredients or processes are used in the production of "white chocolate".

6. The existing standards for sweet chocolate and milk chocolate, and for the other chocolate products cited above, include minimum requirements for the addition of chocolate liquor, which contains ground cacao nibs. "White chocolate" contains the cacao fat from ground cacao nibs, but not the dark chocolate solids found in chocolate liquor.

7. The purpose of effecting the proposed variation is to facilitate the market testing of "white chocolate" in the United States, under the statement of identity that is in common use in other countries and is most informative to the consumer. Additionally, the market test will facilitate the collection of data on consumer acceptance of the product to support the petitions for a standard of identity for "white chocolate" already on file with the Food and Drug Administration, as cited above.

   A sound legal case can be made that no permit or new standard is needed to authorize the sale of "white chocolate" in this country. Indeed, "white chocolate" almost certainly is an appropriately descriptive statement of identity, independent of the existing standards.

Nevertheless, we acknowledge the Agency's apparent preference for the use of the temporary marketing permit process in this case. For that reason, we are filing this notification.

8. The variation from existing standards would benefit consumers by making it easy for them to distinguish real "white chocolate" products from products made with cheaper cacao fat substitutes. Additionally, the removal of dark cocoa solids from the chocolate formula results in a unique milky white color and a strong milky flavor that seems to be preferred by many consumers.

9. The label for the Baker's Brand Premium Baking Chocolate - White Chocolate Chunks that Kraft plans to add to the ongoing market test is attached.

10. During the market test we expect to distribute on an annual basis 88,000 Lb. of Baker's 12 oz. Premium white chocolate chunks.

11. The product will be distributed throughout the United States.

12. The product will be manufactured by Barry Callebaut USA, Inc., 400 Industrial Park Road, St. Albans, VT 05478-1875. The telephone number for this facility is (802) 524-9711. At this time, the plant manager is Chris Demambro and the Quality Manager is Stuart Redfield.

Please do not hesitate to contact me at 914-335-6548 or in my absence, Sherry Marcouiller at 847-646-4206, if you need additional information. Thank you for your cooperation.

Respectfully submitted,

Paula Nothofer

Kraft Foods, Inc.
Paula M. Nothofer
Regulatory Compliance - Labeling

cc: Sheryl A. Marcouiller
Senior Food and Drug Counsel

Attachment

74750

HOGAN & HARTSON
L.L.P.

Writer's Direct Dial:
202-636-6456

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910
WWW.HHLAW.COM

February 2, 2001

BY HAND DELIVERY

MAR - 1 2001

Loretta A. Carey
Food Standards Branch (HFS-158)
Division of Programs and Enforcement Policy
Office of Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Re: Baker's Brand Premium White Chocolate Chunks – Notice of Participation in Extended Market Test of White Chocolate

Dear Ms. Carey:

As a follow-up to our conversation earlier today, I am providing some additional information with regard to the above-referenced notice of participation for Baker's Brand Premium White Chocolate Chunks, submitted by Kraft Foods, Inc. (Kraft) on January 2, 2001. First, I have enclosed a copy of the revised label for the product. As we discussed, it bears the words "Distributed by" fully spelled out on the information panel.

Second, I understand that you will be talking with CFSAN colleagues about the appropriateness of using the abbreviation "Dist." in place of the words "Distributed by". To facilitate your discussions, I thought it might be helpful to share some information as to why Kraft believes this abbreviation is fully consistent with FDA regulations and policy.

Specifically, I have attached a copy of Section 201.1(h) of the agency's drug labeling rules, and the corresponding preamble discussion. These documents reflect a determination by the agency to permit abbreviations of the phrases used to identify a product's packer or distributor so long as those abbreviations are clear and unambiguous. Because no consumer reasonably could misconstrue the letters

"Dist." as indicating that Kraft is the product's manufacturer (rather than distributor), Kraft is confident that this abbreviation meets that standard. As you can see from the attached correspondence, USDA reached the same conclusion many years ago with regard to the labeling of meat products.

Section 101.5 – the pertinent regulation with regard to the labeling of foods – is fully consistent with Section 201.1(h)'s allowance for abbreviations. Although the phrase "Distributed by" is spelled out in that regulation, it is offered only as an example of the phrases that meet the regulatory requirement.

When Kraft submitted its notice of participation for Baker's Brand Premium White Chocolate Chunks last month, it had every reason to believe that CFSAN would follow the logic reflected in the agency's drug labeling rules. The policy objectives of Sections 201.1(h) and 101.5 are, after all, identical, namely to identify for regulators and consumers the entity responsible for a product in the event of problems or concerns. CFSAN's sudden objection to the "Dist." abbreviation – which Kraft has used for many years on a wide variety of food products – simply was not and could not have been anticipated.

As the enclosed label demonstrates, Kraft has proceeded to revise the label for Baker's Brand Premium White Chocolate Chunks to spell out the words "Distributed by". An inventory of labels bearing the abbreviation "Dist.", however, does exist. I look forward to speaking with you and your colleagues about those labels, as well as the status of the notice of participation for Baker's Brand Premium White Chocolate Chunks on Monday, February 5.

Sincerely,

Andrea M. Bruce

Andrea M. Bruce

Enclosures

cc: Sheryl A. Marcouiller, Esq.

(2) If the person performs at least one applicable operation listed in paragraph (b) of this section and identifies by appropriate designation all other persons who have performed the remaining applicable operations, e.g., "Made by (Person A), Filled by (Person B), Sterilized by (Person C)"; or

(3) If the person performs at least one applicable operation listed in paragraph (b) of this section and the person is listed along with all other persons who have performed the remaining applicable operations as "joint manufacturers." A list of joint manufacturers shall be qualified by the phrase "Jointly Manufactured By _____," and the names of all of the manufacturers shall be printed together in the same type size and style; or

(4) If the person performs all applicable operations listed in paragraph (b) of this section except for those operations listed in paragraph (d) of this section. For purposes of this paragraph, person, when it identifies a corporation, includes a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.

(d) The Food and Drug Administration finds that it is the common practice in the drug industry to contract out the performance of certain manufacturing operations listed in paragraph (b) of this section. These operations include: (1) Soft-gelatin encapsulating, (2) aerosol filling, (3) sterilizing by irradiation, (4) lyophilizing, and (5) ethylene oxide sterilization.

(e) A person performs an operation listed in paragraph (b) of this section only if the operation is performed, including the performance of the appropriate in-process quality control operations, except laboratory testing of samples taken during processing, as follows:

(1) By individuals, a majority of whom are employees of the person and, throughout the performance of the operation, are subject to the person's direction and control;

(2) On premises that are continuously owned or leased by the person and subject to the person's direction and control; and

(3) On equipment that is continuously owned or leased by the person. As used in this paragraph, person, when it identifies a corporation, includes a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.

(f) The name of the person represented as manufacturer under paragraph (b) or (c) of this section must be the same as either (1) the name of the establishment (as defined in § 207.3(b) of this chapter) under which that person is registered at the time the labeled product is produced or (2) the registered establishment name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control. In addition, the name shall meet the requirements of paragraph (g) of this section.

(g) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporate person, only by the actual corporate name, except that the corporate name may be the name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control. The corporate name may be preceded or followed by the name of the particular division of the corporation. "Company," "Incorporated," etc., may be abbreviated or omitted and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(h)(1) Except as provided in this section, no person other than the manufacturer, packer, or distributor may be identified on the label of a drug or drug product.

(2) The appearance on a drug product label of a person's name without qualification is a representation that the named person is the sole manufacturer of the product. That representation is false and misleading, and the drug product is misbranded under section 502(a) of the act, if the person is not the manufacturer of the product in accordance with this section.

(3) If the names of two or more persons appear on the label of a drug or drug product, the label may identify which of the persons is to be contacted for further information about the product.

(4) If a trademark appears on the drug or drug product label or appears as a mark directly on the drug product (e.g., tablet or capsule), the label may identify the holder or licensee of the trademark. The label may also state whether the person identified holds the trademark or is licensee of the trademark.

(5) If the distributor is named on the label, the name shall be qualified by one of the following phrases: "Manufactured for _____", "Distributed by _____", "Manufactured by _____ for _____", "Manufactured for _____by _____", "Distributor: _____", "Marketed by _____". The qualifying phrases may be abbreviated.

(6) If the packer is identified on the label, the name shall be qualified by the phrase "Packed by _____" or "Packaged by _____". The qualifying phrases may be abbreviated.

(i) The statement of the place of business shall include the street address, city, State, and ZIP Code. For a foreign manufacturer, the statement of the place of business shall include the street address, city, country, and any applicable mailing code. The street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply to consumer commodity labels developed or revised after July 1, 1969. In the case of nonconsumer packages, the ZIP Code shall appear either on the label or the labeling (including the invoice).

(j) If a person manufactures, packs, or distributes a drug or drug product at a place other than the person's principal place of business, the label may state the principal place of business in lieu of the actual place where such drug or drug product was manufactured or packed or is to be distributed, unless such statement would be misleading.

(k) Paragraphs (b), (c), (d), (e), and (f) of this section, do not apply to the labeling of drug components.

(l) A drug product is misbranded under section 502(a) of the act if its labeling identifies a person as manufacturer, packer, or distributor, and that identification does not meet the requirements of this section.

(m) This section does not apply to biological drug products that are subject to the requirements of section 351 of the Public Health Service Act, 42 U.S.C. 262.

[45 FR 25775, Apr. 15, 1980; 45 FR 72118, Oct. 31, 1980, as amended at 48 FR 37620, Aug. 19, 1983]

§ 201.2 Drugs and devices; National Drug Code numbers.

The National Drug Code (NDC) number is requested but not required to appear on all drug labels and in all drug labeling, including the label of any prescription drug container furnished to a consumer. If the NDC number is shown on a drug label, it shall be displayed as required in § 207.35(b)(3) of this chapter.

[40 FR 52002, Nov. 7, 1975]

§ 201.5 Drugs; adequate directions for use.

Adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.") Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application (in relation to time of meals,

"Manufactured to the Specifications of ———" are any more likely to mislead a consumer as to the identity of the manufacturer than the phrases permitted by the final regulation, the agency believes that these phrases can be misleading in suggesting that a product made to one distributor's specifications is superior in quality to equivalent products marketed by other firms. As noted in the proposed rule on therapeutically equivalent drug products, "Except for identified problems of bioinequivalence, FDA is not aware that any therapeutically significant differences currently exist among pharmaceutically equivalent drug products which result from differences between public compendial (or antibiotic) standards and higher internal standards of manufacturers." FDA thus believes that even when the written specifications for a product are more demanding than those of generically equivalent products, the differences in specifications do not ordinarily produce a difference in product quality. Because the phrases cited in the comment have the potential to mislead consumers to believe that a product made to the specifications of one distributor is superior to equivalent products, the agency concludes that these phrases should not be allowed.

31. One comment asked for clarification of the provision in § 201.1(h) (§ 201.1(f) as proposed) which states that "No person except the manufacturer, packer, or distributor may be identified on the label of a drug or drug product". The comment stated its assumption that any one, or any combination of these three persons, may appear on the label. The comment noted that many States currently require identification on a drug product label of both the manufacturer and distributor, if the product is distributed by a person other than the manufacturer.

The applicable statute (section 502(b)(1) of the act) and regulation (21 CFR 201.1), while requiring the identification of the manufacturer, packer, or distributor, do not prohibit a firm from identifying any two or all three of these persons on the same drug label.

"Innovators and Developers"

32. Several comments urged that the regulation allow the product label to bear the name of the innovator or developer identified as such. The comments contended that while usually a product's developer (or innovator) would also be the product's distributor (even if not the product's manufacturer), to identify the developer as a distributor would not fully disclose the extent of that person's contribution.

Although the agency recognizes the valuable contribution that a product developer (or innovator) makes, and agrees that a distributor identification of a developer may be somewhat inadequate, it believes that to permit a developer to be identified as such on the product label would detract from the prominence and conspicuousness that must under section 520(c) of the act be accorded words and statements that are required to appear on the label (including statements required to appear under section 502(b)(1) of the act). Therefore, the agency rejects these comments.

33. One comment stated that § 201.1(h) (§ 201.1(f) as proposed) is deficient in that it allows the identification of the manufacturer with the option to omit the name of the packager or distributor who actually delivers the product into interstate commerce. The comment contended that if a manufacturer produces a product for several distributors who are not identified on the product label, in the event of a recall or mislabeling, it might be impossible to ascertain who was responsible for the product.

This comment incorrectly assumes that the agency has the authority to require the distributor or packer to be identified on the drug product label. No statutory provision gives the agency such authority. What is required under the Federal law is that the drug product label bear the name of the manufacturer, packer, or distributor. The choice of which of these persons or which combination of these persons are to be identified is left to the labeler of the product and to the requirements of State law.

Even without the authority to require that a drug product label identify the person who is directly responsible for introducing the product into interstate commerce, the agency believes that there are adequate mechanisms to determine who, in fact, was so responsible and thus to trace products that are subject to a recall or to an action to correct a misbranding.

Abbreviations

34. One comment urged that § 201.1(h) (§ 201.1(f) as proposed) be revised to permit a label to contain abbreviations of the phrases used to identify the packer and distributor. The comment stated that the use of an abbreviation, such as "Dist.", adequately informs consumers that the named person is not the manufacturer. A comment stated further that the failure to give any facts to support the belief that the use of abbreviations is misleading is itself grounds to invalidate the provision under *Almay, Inc.* v. *Califano*, 569 F.2d 674, 682 (D.C. Cir., 1977).

The agency agrees that abbreviations should be permitted of those phrases that § 201.1(h) allows in identifying the distributor and packer. Such abbreviations, of course, should be clear and unambiguous.

Trademark

35. Several comments noted that § 201.1(h) (§ 201.1(f) as proposed) would limit the persons identified on the drug product label to the manufacturer, packer, or distributor of the drug product. The comments urged that the owner of a trademark who licenses the trademark to another company should also be allowed to be identified on the label as the owner of the trademark. The comments argued that identification of the licensor of the trademark on the label is regarded as good trademark practice. One comment stated that a recent Canadian court decision held that a trademark owner may lose his or her rights in the trademark if the licensed product label does not state who owns the trademark. The comment claimed that other countries follow the Canadian practice. Finally, one comment suggested that along with permitting the identification of the trademark licensor, the proposal should permit the identification on the label of the licensee as a licensee.

The agency did not intend to compromise the rights of a trademark holder in its trademark. Section 201.1(h) has been revised to state that both the licensor and licensee of a trademark that appears on the drug product or product label may be appropriately identified on the drug product label.

Logos

36. Several comments recommended that proposed § 201.1(g) be deleted. That section would require, if a person's name, mark, imprint, or other identifying written, printed or graphic matter (i.e., product "logo") appeared directly on the drug product, that the label state whether the person identified on the product is the manufacturer, packer, or distributor. One comment argued that the provision would discourage the use of logos by persons who might not qualify as the manufacturer under the terms of the regulation. Another comment took issue with the stated justification for the requirement. The comment noted that the preamble justifies the proposed requirement by stating that use of a logo has the potential to mislead consumers by leading consumers to believe that the

UNITED STATES DEPARTMENT OF AGRICULTURE
CONSUMER AND MARKETING SERVICE
WASHINGTON, D.C. 20250

October 2, 1967

Mr. Merrill S. Thompson
Chadwell, Keck, Kayser,
Ruggles & McLaren
135 South LaSalle Street
Chicago, Illinois 60603

Dear Mr. Thompson:

Reference is made to your letter of August 22, 1967, and our previous telephone conversation regarding the abbreviation "Dist." in lieu of "Distr." used by Kraft Foods Division of National Dairy Products Corporation.

We have completed our review of the documents and comments offered regarding this matter.

We are agreeable to the continued use of the abbreviation "Dist." for the word "Distributor" used by Kraft Foods on their labels for meat food products.

I certainly appreciate your cooperation and assistance in this matter, and trust that this has been a satisfactory solution of the problem.

Sincerely yours,

H. E. Steinhoff, Staff Officer
Meat Labels Group
Labels, Standards, and
Packaging Branch
Technical Services Division