

Food and Drug Administration Rockville MD 20857

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JAN = 5 2001

Ms. JoAnn Hamamura, M.S., C.N.S. Sr. Labeling and Regulatory Specialist Quality Management, Regulatory and Nutrition Nestlé Food Company 800 North Brand Blvd. Glendale, California 91203

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Re:

21 CFR 130.17(f) - Amendment of Temporary Marketing Permit for "White

Chocolate" under Docket No. 93P-0310

Dear Ms. Hamamura:

This is to acknowledge your letters of May 19, 2000, and November 30, 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). Previously, in a letter dated September 25, 1995, FDA granted a permit to Nestlé Food 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 "Nestlé NestEggs White Chocolate Crunch." The permit was amended on December 11, 1995, December 21, 1995, June 20, 1996, September 20, 1996, January 23, 1997, October 20, 1997, and, July 24, 1998, to provide for an additional total of 4,267,030 kilograms (9,407,225 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 "Solid White Chocolate" and will be sold in the shape of a bunny.

The white chocolate component of the product 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) safe and suitable antioxidants are added. In all other respects, the white chocolate component would conform to the cacao product standards.

Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes, of 36,281 kilograms (80,000 pounds) annually. This amount is in addition to the 4,267,030 kilograms (9,407,225 pounds) currently provided for under the September 25, 1995, temporary permit and subsequent amendments.

The product will be manufactured for Nestlé Food Company at Chris Candies Inc., 1557 Spring Garden Avenue, Pittsburgh, PA, 15212, and will be distributed nationwide. All other conditions of the temporary permit remain the same.

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The draft labels that you submitted for the test food are acceptable for the purpose of this market test. 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 products are 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 J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling, and Dietary Supplements Center for Food Safety and

Applied Nutrition