

Sub

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P-0150]

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Iceberg Water Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Canada Ice Enterprises, Inc., to market a product designated as "80 degrees north Iceberg Water" that deviates from the U.S. standard of identity for bottled water. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than *[insert date 3 months after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice

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that a temporary permit has been issued to Canada Ice Enterprises, Inc., P.O. Box 722, St. Anthony, NL A0K 4S0.

This permit covers limited interstate marketing tests of products identified as “80 degrees north Iceberg Water” that deviate from the U. S. standard of identity for bottled water (§ 165.110 (21 CFR 165.110)) in that the source of the water is an iceberg. The test product meets all the requirements of the standard with the exception of the source definition. The purpose of this permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of 500,000 cases of 24 x 500 milliliter bottles and 500,000 cases of 12 x 1 liter bottles, totaling 1 million cases per year. The total fluid quantity covered by this application is 12 million liters (3,170,065 gallons). The test product will be manufactured for Canada Ice Enterprises, Inc., 10 Cremilliere Rd., St. Anthony, NL Canada A0K 4S0. Canada Ice Enterprises, Inc., will distribute the test products throughout the United States. The information panel of the labels must bear nutrition labeling in accordance with 21 CFR 101.9. The bottled water must be manufactured in accordance with the quality standards in § 165.110(b) and the requirements for processing and bottling of bottled drinking water in 21 CFR part 129. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than (*see DATES*).

Dated: 4/20/07

April 20, 2007.

Barbara Schneeman

Barbara Schneeman,
Director, Office of Nutritional Products, Labeling and Dietary Supplements,
Center for Food Safety and Applied Nutrition.

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