



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

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OCT 6 2005

Mr. Roger F. Friedman, Esq.
Rutan & Tucker, LLP
611 Anton Boulevard
Fourteenth Floor
Costa Mesa, CA 92626-1931

Re: Docket No. 2005P-0376

Dear Mr. Friedman:

This is in response to your application on behalf of Canada's Original ICEBERG Water Corp. to the Food and Drug Administration (FDA) for a temporary permit to market test, in interstate commerce, "iceberg water" a product that will deviate from the U.S. standard of identity for "bottled water" (21 CFR 165.110) in that the source of the water is an iceberg and the name of the product is "Canada's Original Iceberg Water." In all other respects, the test product will conform to the standard for bottled water.

Relying on the representations made in your application, we are hereby granting your request to make interstate shipments, for market testing purposes of 500,000 cases of the 24 x 500 ml bottles and 500,000 cases of the 12 x 1 liter bottles, totaling 1,000,000 cases per year. The total fluid weight of the test product is 12,000,000 liters (3,170,065 gallons) of the test product. You must submit finished labels to the Team Leader, Regulations and Review Team, Food Labeling and Standards Staff (HFS-820), Office of Nutritional Products, Labeling, and Dietary Supplements, before you ship the product in interstate commerce. The test product will be manufactured for Canada's Original ICEBERG Water Corporation by Discovery Springs, Daniel's Point Road, located at Trepassey, Newfoundland, Canada A0A 4B0 and distributed nationwide in the United States. The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. The bottled water will be manufactured in accordance with the quality standard in 21 CFR 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 you introduce or cause the introduction of the test product into interstate commerce, but not later than 3 months after notice of issuance of the permit is published in the Federal Register. Before you test market the product, you must notify FDA, in writing, of the date the 15-month period will begin.

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While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of "Canada's Original Iceberg Water" covered by this permit on the grounds that the food fails to comply with the standard(s) of identity for bottled water (21 CFR 165.110) because of the deviations provided for in the TMP.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara Schneeman". The signature is written in a cursive, flowing style.

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