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August 3, 2004

**VIA FEDEX**

Team Leader, Conventional Foods Team  
Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition (HFS-822)  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Application for (1) Permit to Participate in Market Test of Iceberg Water,  
and (2) Amendment to 21 C.F.R. § 165.110 to Include "Iceberg Water" as a  
Standard of Identity

Dear Sir or Madam:

Rutan & Tucker, LLP is counsel to Canada's Original ICEBERG Water Corporation with respect to the matters addressed in this letter, and we write to you on its behalf.

In September 2000, the Food and Drug Administration ("FDA") granted the application of Iceberg Industries Corporation ("Iceberg Industries") for a temporary permit to market test, in interstate commerce, a product to be designated as "Borealis Iceberg Water," Docket Number 00P-1439, Federal Register, Volume 65, Number 174, September 7, 2000.

In September 2001, Iceberg Industries filed an application for amendment to 21 C.F.R. § 165.110 to include a standard of identity for "Iceberg Water." On or about March 22, 2002, the FDA informed Iceberg Industries that it would not be taking action on the petition at that time, but would later consider how to most appropriately address the application within the FDA's overall strategy to reinvent food standards.

In June 2002, the FDA granted Iceberg Industries' application for an extension of its marketing permit, Docket Number 00P-1439, Federal Register, Volume 67, Number 124, June 27, 2002. At that time, the FDA invited interested persons to participate in the market test under the conditions that applied to Iceberg Industries with respect to the composition of the test product. It is our understanding that Iceberg Industries' permit is no longer in effect and its file has been closed, perhaps due to the fact that it is no longer in business, and therefore, any party wishing to participate in a market test of "Iceberg Water" must submit a new application.

2005P-0376

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We are therefore pleased to present on behalf of Canada's Original Iceberg Water Corporation this application, in accordance with the requirements of 21 C.F.R. § 130.17, to participate in a market test of "Iceberg Water," like the market test described in Federal Register Volume 67, Number 124, June 27, 2002, and for amendment to 21 C.F.R. § 165.110 to include "Iceberg Water" as a standard of identity for bottled water.

The name and address of the applicant is:

Canada's Original Iceberg Water Corporation  
23 Lesmill Road, Suite 304  
Toronto, Ontario  
Canada, M3B-3P6

The name and address of counsel for the applicant is:

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

Canada's Original Iceberg Water Corporation and its sister corporation, Canadian ICEBERG Vodka Corp., are regularly engaged in producing the following iceberg products: "Canada's Original ICEBERG Water" and "Canadian ICEBERG Vodka."

The standards of identity for bottled water are set forth in 21 C.F.R. § 165.110. The proposed variation from the standards of identity is limited to the bottled water product being "Canada's Original ICEBERG Water." The water source, icebergs, is not provided as a standard of identity within the Code of Federal Regulations. We are therefore requesting approval for the addition of "Iceberg Water" to 21 C.F.R. § 165.110 as a standard of identity so as to permit the use of this term on the product label. In this context, the term "iceberg" is a large floating mass of ice that has detached from a glacier.

The proposed iceberg water product "Canada's Original ICEBERG Water" is wholesome and nondeleterious. The source of the product is icebergs that are comprised of fresh, sodium-free, pollutant-free water. Canada's Original ICEBERG Water is a single-ingredient product that is filtered three times and treated with ozone. It is bottled under strict quality control procedures and with the utmost care. The product is also subjected to appropriate analysis by certified laboratories to ensure that the product is safe and nutritious, which is required by the Canadian Food Inspections Agency, the official Canadian government regulatory agency governing all food products in Canada. The product complies with all applicable

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Canadian regulations regarding bottled water. A true and correct copy of a recent laboratory analysis of Canada's Original ICEBERG Water is enclosed with this application.

The proposed amendment to 21 C.F.R. § 165.110 will result in the addition of "Iceberg Water" as a standard of identity. No new ingredient will be added, and no ingredient required by the standard of identity will be eliminated.

The purpose of the variation to 21 C.F.R. § 165.110 is to authorize the use of "Iceberg Water" as the standard of identity on product labels and in advertising. This description is both truthful and precise, and can be verified with the documentation that has been enclosed for your information.

The proposed amendment to the standards of identity is of potential advantage to consumers because it would provide a clearly designated source of the water, and clarify any possible confusion about the type of water in the bottle. "Iceberg Water" denotes a water source that is different from any other source on the planet. None of the standards of identity currently included in 21 C.F.R. § 165.110 accurately identify the type of water. The term "Iceberg Water" provides a clear, accurate, and precise explanation of the water.

We enclose with this application colored copies of the draft labels for the bottles and packaging that the applicant proposes to utilize under this application. The labels are for the two different bottle sizes that will be marketed and sold in interstate commerce: 500 milliliter and 1 liter. Actual labels will be forwarded to you upon request.

The applicant is seeking a fifteen-month term for this temporary marketing permit. During the permit term, the applicant will continue to develop and implement its marketing plan and strategies for distribution of this wholesome and nondeleterious product in interstate commerce. The requested term will give the applicant the opportunity to proceed with a detailed analysis of the growth and acceptance of "Iceberg Water" in the United States markets, and to begin implementing its marketing and distribution initiatives.

The applicant is not aware of any prior applicants, except for Iceberg Industries, that sought to test market "Iceberg Water" in the United States. The applicant is informed, however, that Iceberg Industries is no longer in business, and the applicant believes that Iceberg Industries never successfully completed its investigation or market test. Accordingly, the applicant requests a temporary marketing permit to gather additional support for this application to amend the standard of identity.

The projected amount of Canada's Original ICEBERG Water that will be distributed during the requested permit term is 500,000 cases of the 24 x 500 ml bottles and 500,000 cases of the 12 x 1 L, totaling 1,000,000 cases per year. The total fluid quantity covered by this

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application is 12,000,000 liters, or the equivalent of approximately 3,170,065 gallons. This amount is necessary to cover the applicant's proposed market test area and its marketing and distribution initiatives, ensure that the applicant is able to meet the anticipated market demand, and produce product within its budgetary constraints.

The areas of distribution are each of the 50 States in the United States of America. This area of distribution is appropriate since Iceberg Industries is no longer exploiting a permit to market test iceberg water, and it is necessary to gather data on as many geographical regions as possible, particularly because preferences vary by area and there are numerous social and environmental differences throughout the United States.

Canada's Original Iceberg Water is manufactured for Canada's Original ICEBERG Water Corporation by Discovery Springs, located at Daniel's Point Road, Trepassey, Newfoundland, Canada A0A 4B0.

It is the applicant's intent to continue to market and distribute Canada's Original ICEBERG Water in the United States and Canada, including in the province where it is manufactured

Distribution through normal marketing and distribution channels (i.e. interstate commerce) is necessary to subject Iceberg Water to the normal challenges associated with mass production, commercial viability, and public acceptance.

If you have any questions, I can be reached at (714) 662-4604 and at the address indicated at the top of this letter.

Sincerely,

RUTAN & TUCKER, LLP

  
Roger F. Friedman

Enclosures