

2007 P-0150

BKG 1



Canada Ice  
ENTERPRISES

2783 7 APR 30 P3:23

November 21, 2006

Loretta Carey  
Center for Food Safety and Applied Nutrition (HFS-820)  
5100 Paint Branch Parkway  
College Park, MD 20740

Dear Ms. Carey:

**This is an ADDENDUM to our previous application for a temporary marketing permit of November 30, 2005 for interstate shipment of experimental packs of water varying from existing definitions and standards of identity.**

(1) Name and Address of Applicant: Canada Ice Enterprises Inc.  
P.O. Box 722  
St. Anthony, NL  
A0K 4S0

Contacts: Rick Pilgrim, Owner/CEO  
Marshall Dean, Owner/President

(11) Probable amount of Product that will be distributed

500,000 cases X 500ml (24 bottles per case) 1,585,032.5 US gallons  
500,000 cases X 1 liter (12 bottles per case) 1,585,032.5 US gallons  
**Total – 3,170,065 US gallons**

(12) The Areas of Distribution

Throughout the United States of America

(13) The address at which product will be manufactured

1-3 Murray's Point Road  
St. Anthony, NF  
Canada  
A0K 4T0

(14) A statement of whether or not such food has been or is to be distributed in the State it was manufactured

“80 degrees north Iceberg Water” will be available for distribution in Newfoundland, Canada.

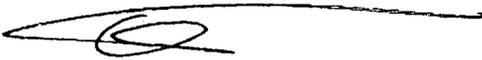
(16) If it has, why it is deemed necessary to distribute to other States

The “80 degrees north Iceberg Water” product is positioned as a premium bottled water product requiring a large consumer base to be economically feasible to Canada Ice. The United States was selected as a trial market due to the large population base and because Canada Ice marketing and sales personnel are based in Houston, Texas.

(16) If it has, why it is deemed necessary to distribute to other States

The "80 degrees north Iceberg Water" product is positioned as a premium bottled water product requiring a large consumer base to be economically feasible to Canada Ice. The United States was selected as a trial market due to the large population base and because Canada Ice marketing and sales personnel are based in Houston, Texas.

Respectfully Yours,



Rick Pilgrim  
Owner/CEO  
Canada Ice Enterprises Inc.  
281.721.6886



8



*The purest  
mountain  
water*

Iceberg Water

500 ml (16.9 FL. OZ.)



80° North Iceberg Water<sup>®</sup>  
comes from icebergs  
born at the top of the world  
in the arctic polar icecap  
where unmatched water purity  
is locked safely in time.

80° North Iceberg Water<sup>®</sup>  
has a velvety smooth taste  
with no added minerals and  
lowest total dissolved solids  
you will find in any water  
on this blue earth.

80° North Iceberg Water<sup>®</sup>  
like arctic people have chosen  
for thousands of years.

You're drinking the  
simplest, healthiest & finest  
water known to mankind.

PURE WATER FOR PURE LIVING

U.P.

No Solids - No Elements  
Produced from 100% Arctic Icebergs  
Canada Ice Enterprises Inc.  
3 Murray's Point Road  
St. Anthony, NL  
Canada A0K 4S0  
For information and questions  
[www.canadaice.ca](http://www.canadaice.ca)





8



*the purest  
the water*

Iceberg Water

1 Liter (33.8 FL OZ.)



80° North Iceberg Water<sup>®</sup>  
comes from icebergs  
born at the top of the world  
in the arctic polar icecap  
where unmatched water purity

is locked safely in time.  
80° North Iceberg Water<sup>®</sup>  
has a velvety smooth taste  
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April 9, 2005

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)  
5100 Paint Branch Parkway  
College Park, MD 20740

Dear Sir/ Madam:

**ADDENDUM II** : APPLICATION FOR TEMPORARY PERMIT FOR INTERSTATE SHIPMENT OF EXPERIMENTAL PACKS OF WATER VARYING FROM EXISTING DEFINITIONS AND STANDARDS OF IDENTITY (Sec. 130.17)

**Regarding questions from Loretta Carey (3/28/05)**

1. **Gross Beta:**  
§165.110 b) (5) (A)

**FDA Request:**

- a) Restate in millirems per year calculated on the basis of an intake of 2 liters of the water per day. Gross Beta (excluding Uranium).
- b) Restate the Uranium content in µg/liter.

**Response:**

- a) The laboratory (National Laboratory) that conducted our analysis refers to the IBWA Model Code stating the Gross Beta Particle and Photon Radioactivity in pCi/L. The measured value was 0.315 pCi/L.

*Barbara Marteney at National Labs is available for further discussion (800) 458-3330 ext. 217 if required.*

**Calculations using a Dose Factor to determine millirem/year.**

For radium-226 the dose factor is  $3.58 \times 10^{-7}$  sieverts (Sv) per becquerel (Bq) ingested (EPA Federal Guidance Reports (FGR) 11 and 12). This more or less equates to  $1.3 \times 10^{-3}$  millirem per picocurie.

The Gross Beta measured is 0.315 pCi/L. Based on 2 litres per day this equates to 230 pCi/L.

Using the above dose factor:

⇒ **Gross Beta is 0.299 millirem/ year.** This is significantly below the maximum value of 4millirems/ year (21CFR165.110 b) (5) (C)).

- b) The FDA 21 CFR Part 165, [Docket No. 03N-0068], Beverages: Bottled Water; Companion Document to Direct Final Rule; in Section III states:

“If uranium is determined by activity-type methods, a 0.67 pCi/μg conversion factor is used to convert activity to mass concentration (65 FR 76708 at 76725)

Therefore, the value of 0.185 pCi/L is equated to (0.185/0.67):

⇒ **0.276 μg/L** This is well below the MCL of 30μg/L.

2. **Test Method:**  
§165.3; §165.110 b) (2)

**FDA Request:**

Please describe the method used to measure the “Total Coliform” indicating the number of samples tested.

**Response:**

The Total Coliform utilized EPA Method 9222B. For an annual source test one sample was used to perform the analysis.

3. **Clarification of SPC Level Detected:**

FDA Request:

Please clarify any conclusion as to the presence of > 5700 CFU/ML in the samples tested. Is this associated with the source water or the container? Is this attributed to the source or the finish process?

Response:

The water tested is source water. The laboratory was not able to provide a definitive reason for the SPC value >5700 CFU/ml. Possible causes include contaminant originating from the sample container during the sampling process. The sample could also have experienced some higher temperatures during transportation which could lead to higher levels of SPC.

The finish water will be treated and regular product monitoring take place to ensure the contaminants are not present in the finished product.

**4. Missing Results:**

FDA Request:

The following results are not included in the independent laboratory report:

- Dichloromethane
- Monochlorobenzene
- Xylenes
- Ethylene Dibromide

Response:

CHEMICAL	REFERENCE	RESPONSE
Dichloromethane (Fed ID #2964)	165.110 (b)(4)(iii)(B)	The result is listed on the 4 <sup>th</sup> line of Page 4 of 5 of the National Testing Laboratories Analytical Report – Organic Chemicals – volatiles.
Monochlorobenzene	165.110 (b)(4)(iii)(B)	This is the same as chlorobenzene which is listed on the 9 <sup>th</sup> line of Page 3 of 5 of the National Testing Laboratories Analytical Report – Organic Chemicals – volatiles.
Xylenes (Fed ID #2955)	165.110 (b)(4)(iii)(B)	The laboratory report indicates o-xylene, m-xylene and p-xylene as “Not Detectable”. National Laboratory indicates “Total Xylenes” is the sum of

		these three constituents.
Ethylene Dibromide	165.110 (b)(4)(iii)(C)	See page 5 of 5: - 1,2 Dibromoethane

**5. Disinfectants:**

**FDA Request:**

**1) How we transport, process and store water.**

**(See attached Process Control Plan)**

The iceberg water will be purchased from local iceberg harvesters on a per ton basis. The water may be in a frozen or liquid form.

Upon receipt of the water it will be stored in FDA approved drinking water tanks. Coliform and HPC will be monitored weekly. Ozonation treatment will be conducted as required to control any presence of bacteria.

The entire source and final water handling, monitoring and treatment will be supervised by a competent person qualified and experienced in the operation, maintenance, sanitation of water processing plant equipment and the maintenance and monitoring of source and product water quality in accordance with industry standards and FDA regulations.

**2) Not clear how we get the water to the bottle**

The water is harvested by an independent supplier. The water is delivered to our harbor front wharf and after is tested for coliform and HPC levels. If acceptable it is pumped into the FDA food grade storage tanks. The water is fed into the adjacent bottling plant with hoses and connections which will be maintained in accordance with our standard operating procedures.

The bottled water filling equipment is commercial grade such as the EZ-PAK computer controlled rinser, washer, filler, capper and wrapping machines in addition to a sleeve applicator and steam shrink tunnel for label application.

**3) Finish water test results**

Canada Ice Enterprises Inc plans to commence full production of bottled water in the summer of 2005. The test results submitted are for the source water and we are confident that the HPC levels can be reduced to acceptable levels with ozonation treatment.

**4) Source Water**

a) Where is source water located?

North Atlantic icebergs come from about 100 glaciers in Greenland and are carried south in the Labrador Current. There are 400 to 800 icebergs that migrate past Newfoundland each year in spring and early summer and can weigh up to several million tons. Many icebergs are over 15,000 years old and are the result of snow accumulation which, over the years, forms glacial ice.

b) Is it protected?

The iceberg ice was formed thousands of years ago as a result of snow accumulation forming the glaciers in Greenland. This was before our current atmospheric and environmental pollution concerns.

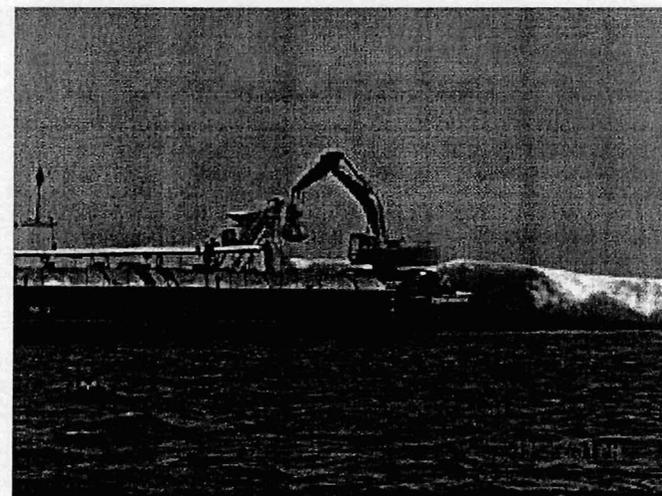
The icebergs are not in one geographic location and they are many and different each year. As a piece of ice breaks from the glacial shelf an iceberg is formed. They drift south and start melting until it is fully dissipated in the ocean.

Due to their frozen state they do not absorb the seawater and the surface is rinsed once it is lifted onto the harvesting ship to maintain quality of the source water.

c) How is it collected?

The water is collected as solid ice form by breaking up the iceberg formation. This can be achieved with a variety of means, but for the purposes of this report, we will describe the method used by our prospective supplier.

This method of iceberg harvesting requires a harvesting barge to be attached through the use of cables (sea-lashing) to a plateau shaped iceberg. See *Figure 4*



There is a backhoe located on the stern of a harvesting barge with a claw attachment on the end of an articulated arm. The mechanism hydraulic fluid is vegetable oil and the equipment is steamed clean twice per day during operation.

Once a suitable iceberg is identified, through visual inspection, the barge is tied to the iceberg and the top 0.5 meters of ice is cleared. Harvesting begins by

digging the iceberg with the claw and placing the ice-chips/snow in a hopper located on the barge.

Water is circulated with the harvested ice-chips and they melt and are pumped in tanks located in the barge hull. The barge will then transport the iceberg product to the Canada Ice Enterprises port to be pumped out and used in iceberg bottled water product.

**6. Label:**

**FDA Request:**

- 1) Iceberg water is not quite 50% the size of the name ICEBERG. FDA's interpretation is that 50% is a good rule of thumb.
- 2) Declaration of quantity shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration (21CFR 101.105 (f)).

**Response:**

Find attached PDF label format showing "Arctic Bay" with 12/32" character height and the source "Iceberg Water" with a character height of 6/32", providing a 50% height.

The declaration of quantity has been separated from the above statement of source by more than the height of the declaration characters.

If there are concerns or questions regarding this application please contact me.

Yours truly,

A handwritten signature in black ink, appearing to read "Mark D Wallace", with a horizontal line underneath.

Mark D Wallace  
Director/ Co-Owner  
Canada Ice Enterprises Inc.  
713.799.5261 (main – Houston, Texas)  
713.202.5433 (cell)