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November 22, 2004

VIA FEDEX

Ms. Linda McCollum
Conventional Foods Team
Div. of Standards & Labeling Regulations
Office of Nutritional Products, Labeling & Dietary Supplements
Center for Food Safety & Applied Nutrition (HFS-822)
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

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

Dear Ms. McCollum:

Pursuant to our recent telephone conversations, enclosed are the following items in support of Canada's Original ICEBERG Water Corporation's above-referenced application: (1) a description of the production processes for Canada's Original ICEBERG Water; (2) two sample bottles (one 500ml/16.9oz and one 1L/33.8oz) of Canada's Original ICEBERG Water with proposed labels.

If you have any additional questions or comments, please call me.

Sincerely,

RUTAN & TUCKER, LLP

Roger F. Friedman

RFF:ap
Enclosures

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Canada's Original ICEBERG Water Corporation
Description of Production Processes

This statement of production processes is submitted in further support of the Application of Canada's Original ICEBERG Water Corporation (the "Applicant"), dated August 3, 2004, for (1) Permit to Participate in Market Test of Iceberg Water, and (2) Amendment to C.F.R. § 165.110 to Include "Iceberg Water" as a Standard of Identity.

The Applicant wishes to market water that is produced by melting ice harvested from fresh-water icebergs naturally occurring in a marine environment. The current regulation, specifically 21 C.F.R. § 165.110, does not recognize icebergs as a potential water source, nor does it recognize melting iceberg ice as a process by which bottled water may be produced. Therefore, there is currently no FDA-approved label designation that reflects the origin or contents of this product. Although this product could be labeled "bottled water" or "drinking water" under the current regulation, these names do not provide sufficient information to allow a purchaser to make an informed decision whether to buy (or not to buy) this product. Moreover, those designations do not adequately describe the pure and wholesome nature of this product.

The harvesting and production processes utilized by the Applicant are similar to those previously utilized by Iceberg Industries under an FDA-approved temporary marketing permit, Docket Number 00P-1439, Federal Register, Volume 65, Number 174, September 7, 2001. Iceberg Industries has ceased operations, gone out of business, and its FDA permit is no longer in effect.

The Applicant currently employs the processes described below to harvest ice from icebergs and produce Iceberg Water products. The Applicant does not believe these are the only processes by which icebergs can be utilized as a bottled water source. But the current processes are described to illustrate that water produced by melting iceberg ice is not included in the current specific standards of identity.

Summary

The following description is a summary of the harvesting and production processes; a more detailed description follows.

Iceberg water is produced with the use of an iceberg harvesting craft (the craft) that has been specifically designed for this process. The craft was previously utilized by Iceberg Industries in its production of Iceberg Water products. The craft is towed to iceberg locations by using an ocean-going tugboat. The craft contains the following essential equipment items:

1. A crane and grapple assembly that can be used to break manageable ice fragments from icebergs.

2. An ice crusher, that reduces harvested ice blocks to fragments that are a few centimeters in size.

3. Six storage tanks that can store approximately 1,000,000 liters of water.

4. A heating system, located beneath the storage tanks, that is used to melt ice.

5. Appropriate transfer pumps to move and circulate water produced from melting ice.

6. On-board treatment equipment used to maintain the purity of water produced at sea. This equipment includes 20-micron filtration and an ultraviolet sterilization system sized for a flow of 200 gallons per minute. Water is continuously circulated through this system while the craft is at sea.

During normal marine operations, the harvesting craft is towed to a suitable iceberg. The crane and grapple are used to break off manageable fragments of ice that are immediately placed in the ice crusher. The ice is ground into small pieces, and is delivered to one of the storage tanks. The heating system is used to melt the ice and thus produce water. The water is continuously circulated through the treatment equipment to maintain purity while at sea.

When the craft returns to port, the water is unloaded into a 225,000-gallon tank farm at the Applicant's production facility. The water is then bottled in a recently-constructed plant that is generally similar to other modern plants in the bottled water industry. Prior to bottling, the water passes through several additional treatment steps that include additional filtration and ozonation.

Technical Description

The following technical description details the Applicant's processes for harvesting of icebergs and production of bottled Iceberg Water.

A. Harvesting Equipment

Iceberg harvesting is conducted at sea using the craft, which was specifically outfitted for this process. The craft is an unpowered ocean-going vessel that is moved to location by an ocean-going tugboat. The primary source area for the icebergs is located off the eastern coast of Newfoundland and Labrador and falls between latitudes 47N and 57N. Icebergs are typically harvested on a seasonal basis between May and November. The icebergs are closer to the 47N latitude at the start of the harvesting season, and as the season progresses, the craft must move further north to find suitable icebergs.

The craft, which is approximately 200 feet in length, carries the following major equipment items:

1. A crane capable of lifting 60 tons, at a boom angle of 60 degrees, which is equipped with a hydraulic grapple. The grapple is used to remove suitably sized (1,000 lb. maximum) pieces of ice from the iceberg.

2. An ice-crushing unit to further reduce the size of ice, once it is on board the craft. The ice crusher hopper is constructed of stainless steel as are the crushing drum and tips.

3. Four, 55,000-gallon potable water storage tanks which have been equipped with a steam-heating system for melting ice. The steam heating pipes are located in the harvesting craft hold beneath the tanks, and do not pass through the tanks. Therefore, there is no possibility of steam leakage into the product water.

4. Two additional 55,000-gallon potable water storage tanks. All the tanks are coated with Devoe Bar Rust 233H which is an NSF-approved potable water epoxy coating.

5. An oil-fired steam-generation system rated at 2,000,000 BTU/hr to produce steam for ice melting.

6. A 10-horsepower transfer pump for use in transferring water from the ice melting tanks to the remaining tanks. All piping to and from the tanks is 2-inch, type 304 stainless steel. This pump is rated at 180 gallons per minute for offloading water; it is, however, adjusted to pump at lower flow rates for water production.

7. Six charcoal-filtration units connected in parallel to give a flow rate of approximately 100 gallons per minute. These units are positioned below deck in a manner that allows them to be easily removed for charcoal changeovers above deck. The charcoal-filtration units are followed by an AMTEC canister filter containing 20 micron cartridges that are capable of a flow rate of 200 gallons per minute, and that capture stray carbon from the charcoal towers.

8. Two ultraviolet sterilizers manufactured by Sterilite, each with a rated flow of 100 gallons per minute. These units are connected in parallel to yield a flow capacity of 200 gallons per minute.

9. An electrical generation system capable of 440 volts 75 KVA.

10. Living quarters for the crew are located on the ocean-going tug boat.

B. Harvesting Operations

Iceberg harvesting is carried out in the following manner.

1. The craft is brought to the harvesting area using the ocean-going tug boat.

2. The tug and craft approach the iceberg from the leeward side. The tug slowly maneuvers the craft close to the iceberg. The craft and iceberg are secured together via a long tether. Weather and sea conditions play a large part in the day-to-day harvesting, and the craft will not harvest in unsafe conditions. Iceberg harvesting takes place during daylight hours only. The May to November harvesting season assures that there is sufficient daylight for cost-efficient operations, and this is the season that icebergs are most readily available for harvest.

3. The crane and grapple are used to break off fragments of ice that are approximately 6" to 24" in diameter weighing a maximum of 1,000 pounds. The claw fingers of the grapple are clad with stainless steel.

4. The ice fragments are immediately delivered by the grapple to the crusher where they are broken into smaller fragments about 3 cubic inches in size. The ice is crushed to aid ice handling and to improve the efficiency of ice melting.

5. The crushed ice is then sent to one of the designated melting tanks by a chute.

6. Ice melting is an on-going procedure that may operate 24 hours per day. As water is produced, it is pumped through the two-stage filtration system, through the ultraviolet sterilizer, and into one of the 55,000-gallon potable water storage tanks. The system typically has a maximum flow rate of 100 gallons per minute.

7. Harvesting proceeds until the two storage and four melting tanks are full. The ship then returns to port.

8. Once in port, the ship offloads water from the storage tanks. The water is pumped through a 4" pipeline to a tank farm for storage.

9. The tank farm is located on a knoll above the bottling plant. This facility consists of nine 25,000-gallon tanks that are manifolded together to give a total capacity of 225,000 gallons. These tanks are fitted with a Clean in Place (CIP) system, and are routinely sanitized prior to each filling.

C. Equipment Sanitization

The following procedures are used to sanitize equipment on the craft:

1. Sanitization of on-board tanks is carried out before each trip to sea. The following procedure is used: Tanks are first rinsed with clear water and flushed completely to drain. A 200 parts per million chlorine solution is then sprayed onto the tank inside surfaces. The surfaces are then hand scrubbed. The tanks are then rinsed with clear water and flushed to waste. The tanks are then rinsed with municipal water and chlorine residual checks are made until the chlorine residual is gone. The tank cover is then sealed with a bolting mechanism and locked.

2. Water lines on the craft are sanitized before each trip to sea. These lines are first rinsed with clear water and flushed to drain. A Dibac-injection system is used to prepare a 200 parts per million chlorinated solution that is circulated within the lines for 15 minutes. The lines are then rinsed, and chlorine residual checks are made until the residual is gone.

3. The grapple and ice crusher are washed and sanitized prior to each day's production using a 200 parts per million chlorine solution and a similar procedure.

D. Bottling

Empty polyethylene terephthalate (PETE) bottles are placed at the beginning of the production line on pallets and moved onto a depalletizer. The bottles are then fed single-file into a conveyor and they move into the bottling facility's "clean room" where they pass through a BEVCO bottle rinser. This process inverts the bottles and passes them through a high-pressure spray of ozonated water. After passing through the rinser, the bottles are turned upright and they move along the conveyor to be filled and capped. The bottle filler and capper unit is a Filler Specialties 24-head, rotary filler with a capacity of 120 bottles per minute. Caps are fed to the

capper by a Filler Specialties automatic cap feeder, which operates on compressed air. Once the bottles are filled and capped, they continue along the conveyor and leave the clean room. They are then labeled and placed in cartons for shipment.

E. Special Precautions

The iceberg harvesting process has been designed to avoid contaminating the production water with petroleum contaminants. The hydraulic systems used for the harvesting process have been designed to operate with food-grade hydraulic fluid. All hydraulic fittings are examined daily for signs of leakage or incipient failure, and if necessary, corrective actions are taken prior to the start of production. If a large hydraulic leak were to occur, it would be evidenced by an equipment malfunction, and potentially affected ice would be discarded. The charcoal filtration system on the harvesting craft is designed to remove any organic materials that might enter the water during processing. In addition, the bottling facility also utilizes a charcoal filtration process, which was installed as another precautionary measure to remove any organic compounds were they to enter the water through an unanticipated path.

The ultraviolet sterilizers and on-board recirculation maintain the water in a sanitary condition on the craft. The bottling plant includes 1-micron absolute filtration and an advanced feedback-controlled ozonation system to assure a sanitary final product.