

Dated: May 4, 2005.

Debbie Powell,

*Director, Office of Operations and
Discretionary Grant Programs,
Administration on Developmental
Disabilities.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000P-1439] (formerly Docket
No. 00P-1439)

Iceberg Industries Corp.; Revocation of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of a temporary permit issued to Iceberg Industries Corp. to market test products designated as "Borealis Iceberg Water" because there is no evidence that the company is operational, and the need for the permit no longer exists.

FOR FURTHER INFORMATION CONTACT: Loretta 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 a notice published in the *Federal Register* of September 7, 2000 (65 FR 54283), FDA issued a temporary permit to Iceberg Industries Corp., 16 Forest Rd., suite 300, St. John's, Newfoundland, Canada, A1C2B9, to market test products identified as "iceberg water," a name that is not permitted under the U.S. standard of identity for bottled water in § 165.110 (21 CFR 165.110). The agency issued the permit to facilitate market testing of products whose labeling differs from the requirements of the standard of identity for bottled water issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covered limited interstate market testing of products that deviated from the standard for bottled water in § 165.110 in that they were identified as "iceberg water" rather than as "bottled water" or one of the other names specified in § 165.110(a)(2). The test product met all the requirements of the standard with the exception of this deviation.

On September 28, 2001, Iceberg Industries Corp. requested that its temporary permit be extended to allow

for additional time for the market testing of its products under the permit in order to gain additional information in support of its petition. In the *Federal Register* of June 27, 2002 (67 FR 43325), FDA announced that it was extending the temporary permit issued to Iceberg Industries Corp. to market test products designated as "Borealis Iceberg Water." The extension allowed the permit holder to continue to collect data on consumer acceptance of products while the agency considered the petition to amend the standard of identity for bottled water, which was submitted by the permit holder. Under the extension, FDA invited interested persons to participate in the market test under the conditions that applied to Iceberg Industries Corp., except for the designated area of distribution. No one accepted the invitation to participate in the market test. In March 2004, FDA attempted to contact Iceberg Industries Corp. to discuss some issues regarding its petition at the telephone number listed in its petition. The telephone number was no longer in service. Attempts to reach the applicant by letter were unsuccessful. Therefore, under 21 CFR 130.17(g)(3), FDA is revoking the Iceberg Industries Corp.'s temporary permit because the need no longer exists.

Dated: May 3, 2005.

Barbara Schneeman,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the *Federal Register* of April 14, 2005 (70 FR 19763). The amendment is being made to reflect a change in the *Date and Time* portion of the document. The start time for each day of the meeting will be changed. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Shalini Jain, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: jains@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), code 3014512535. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of April 14, 2005, FDA announced that a meeting of the Drug Safety and Risk Management Advisory Committee would be held on May 18 and 19, 2005, from 8:30 a.m. to 5 p.m. On page 19763, in the third column, the *Date and Time* portion of the meeting notice is amended to read as follows:

Date and Time: The meeting will be held on May 18 and 19, 2005, from 8 a.m. to 5 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: May 3, 2005.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long- Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary of Health and Human Services (the Secretary) and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand study by the U.S. Air