Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Peter Pan Seafoods, Inc., 2200 Sixth Ave., suite 1000, Seattle, WA 98121.

The permit covers limited interstate marketing tests of products identified as (1) Deming's ''Skinless & Boneless Pink Salmon'' and ''Skinless & Boneless Red Sockeye Salmon'' and (2) Double''Q'' ''Skinless & Boneless Pink Salmon'' and ''Skinless & Boneless Red Sockeye Salmon.'' These canned salmon products may deviate from the U.S. standard of identity for canned Pacific salmon (21 CFR 161.170) in that the products are prepared by removing the skin and bones of the salmon used and, therefore, in lieu of the optional forms of pack provided in 21 CFR 161.170(a)(3), this temporary marketing permit provides for an alternate ''skinless and boneless'' form of pack. The test product meets all the requirements of the standard with the exception of the ''skinless and boneless'' form of pack. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of not more than 1.13 million pounds (or 513 thousand kilograms) of the test product annually. The test products will be manufactured by Peter Pan Seafoods, Inc., at its Valdez Facility, P.O. Box 1027, Valdez, AK 99686–1027 and Dillingham Facility, P.O. Box 410, Dillingham, AK 99576. The test products will be distributed by Peter Pan Seafoods, Inc., throughout the United States except Alaska. The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the product into interstate commerce, but not later than July 27, 2007.

Dated: April 20, 2007.

Barbara Schneeman,

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

[FR Doc. E7–8039 Filed 4–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0150]

Iceberg Water Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Canada Ice Enterprises, Inc., to market a product designated as ''80 degrees north Iceberg Water'' that deviates from the U.S. standard of identity for bottled water. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than July 27, 2007.

FOR FURTHER INFORMATION CONTACT: Loretta A. 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 accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Canada Ice Enterprises, Inc., P.O. Box 722, St. Anthony, NL A0K 4S0.

This permit covers limited interstate marketing tests of products identified as ''80 degrees north Iceberg Water'' that deviate from the U.S. standard of identity for bottled water (§ 165.110 (21 CFR 165.110)) in that the source of the water is an iceberg. The test product meets all the requirements of the standard with the exception of the source definition. The purpose of this permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of 500,000 cases of 24 x 500 milliliter bottles and 500,000 cases of 12 x 1 liter bottles, totaling 1 million cases per year. The total fluid quantity covered by this application is 12 million liters (3,170,065 gallons). The test product will be manufactured for Canada Ice Enterprises, Inc., 10 Cremilliare Rd., St. Anthony, NL Canada A0K 4S0. Canada Ice Enterprises, Inc., will distribute the test products throughout the United States. The information panel of the labels must bear nutrition labeling in accordance with 21 CFR 101.9. The bottled water must be manufactured in accordance with the quality standards in § 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 the food is introduced or caused to be introduced into interstate commerce, but not later than (*see* **DATES**).

Dated: April 20, 2007.

Barbara Schneeman,

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

[FR Doc. E7–8040 Filed 4–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0068]

Medical Device User Fee and Modernization Act; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of April 18, 2007 (72 FR 19528). The document announced a public meeting on April 30, 2007, to discuss the agency's proposed recommendations for the reauthorization of the Medical Device User Fee and Modernization Act of 2002 (MUDFMA I) for fiscal years 2008 through 2012, as well as other proposals to improve the review of medical devices and the third party

inspection program. The correction is being made to reflect a change in location for the April 30, 2007, meeting. The location of the meeting is being changed because of water damage in the original meeting location.

FOR FURTHER INFORMATION CONTACT: *For information regarding this notice and the original notice, contact*: Erik Mettler, Office of Policy and Planning, Food and Drug Administration (HF–11), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX 301–594–6777, email: *Erik.Mettler@fda.hhs.gov*. *For information regarding registration, contact*: Cynthia Garris, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration (HFZ–220), 1350 Piccard Ave., Rockville, MD 20850, 240–276–3150 ext. 121, FAX: 240–276–3151, email: *cynthia.garris@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 07–1919, appearing on page 19528 in the **Federal Register** of Wednesday, April 18, 2007, the following correction is made:

1. On page 19528, in the third column, the first sentence under ''**ADDRESSES**'' is corrected to read ''The public meeting will be held at the Food and Drug Administration, White Oak site, at 10903 New Hampshire Ave., Silver Spring, MD 20993, Bldg. 2, rm. 2031.''

Dated: April 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–2085 Filed 4–24–07; 3:18 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0441]

Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#136) entitled ''Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods.'' This guidance provides our recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance document to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rebecca L. Owen, Center for Veterinary Medicine (HFV–141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9842, e-mail: *rebecca.owen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 14, 2006 (71 FR 66335), FDA published a notice of availability for a draft guidance entitled ''Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods'' giving interested persons until January 29, 2007, to comment on the draft guidance. No comments were received. Therefore, the final guidance has not been substantively changed from the draft version.

Section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) establishes the requirements for a new animal drug approval. FDA regulations specify the information you (the sponsor) must submit as part of your new animal drug application (NADA) and the proper format for the NADA submission (§ 514.1 (21 CFR 514.1)). As part of your NADA submission, you must describe analytical procedures capable of determining the active component(s) of the new animal drug within a reasonable degree of accuracy and of assuring the identity of such components (21 CFR 514.1(b)(5)(vii)). This includes a description of practicable methods of analysis (assay methods) that have adequate sensitivity to determine the amount of the new animal drug in the final dosage form (21 CFR 514.1(b)(5)(vii)(*a*)). In the case of a Type A medicated article, the Type C medicated feed is a final dosage form used to treat the animal. Thus, as part of the NADA review process, FDA looks at assay methods for determining the amount of a new animal drug in Type C medicated feed.

This guidance provides recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method. Many testing laboratories, including state feed laboratories and contract laboratories, use Type C medicated feed assay methods to determine whether the drug in a medicated feed is within the assay limits. The term ''assay limits'' refers to the amount of the drug detected when a Type B/C feed is assayed. The limit is a range that is codified at 21 CFR 558.4(d). When feed assay values fall within this range, it indicates that the feed has been prepared with the correct amount of Type A medicated article. Because many different laboratories use medicated feed assays, it is important that the assay methods are reproducible. Sponsors should conduct method transfer studies to evaluate reproducibility. A method transfer study is part of the evaluation process for a Type C medicated feed assay method and demonstrates the transferability of the feed assay method among different laboratories by comparing the results each laboratory obtains when using the method to analyze a specific set of feed samples. Sponsors may expand the method transfer study to include other medicated feed products, such as Top Dress Type C, Free-Choice Type C, and Type B medicated feeds.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 514.1 have been approved under OMB Control Nos. 0910–0032 and 0910–0154.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).