2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: November 13, 1998

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–30874 Filed 11–13–98; 3:10 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0880]

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 Iceberg Industries Corp. to market test a product designated as ''Borealis 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, in support of a petition to amend the standard of identity for bottled water.

DATES: 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 February 16, 1999.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

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 Iceberg Industries Corp., 447 Kenmount Rd., Box 13518, St. John's Newfoundland, Canada A1B 4B7.

The permit covers limited interstate marketing tests of products identified as ''borealis iceberg water'' that deviates from the U.S. standard of identity for bottled water (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. Because test preferences vary by area, along with social and environmental differences, the purpose of this permit is to test the product throughout the United States.

Under this temporary permit, the bottled water will be test marketed as ''Borealis Iceberg Water.''

This permit provides for the temporary marketing of 75,000 cases of the 24 x 350 milliliters and another 75,000 cases of the 12 x 1 liters (L), giving 150,000 cases in total. The total fluid weight of the test product will be 403,694 gallons or 1,530,000 L. The test product will be manufactured at Enterprise Atlantic Limited Water Bottling Plant, Daniel's Point, Trepassy, Newfoundland, Canada A0A 4B0. The product will be distributed throughout the United States.

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 food is introduced or caused to be introduced into interstate commerce, but not later than February 16, 1999.

Dated: November 5, 1998.

Elizabeth Campbell,

Acting Director, Office of Food Labeling, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–30607 Filed 11–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0946]

Expansion of Medical Device Industry Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) initiated a pilot program in 1996 involving the medical device industry. This pilot program, which was formally adopted in 1997, was shown to optimize resource utilization, enhance FDA/industry communication, and provide firms prompt closure to corrected inspection observations and nonviolative inspections. This program includes eligibility criteria and procedures for preannounced inspections, the annotation of items on form FDA–483–List of Observations (FDA–483) with promised or completed corrections, and postinspection notification to establishments regarding their compliance status.

DATES: The pilot program is effective January 1, 1999. Written comments should be submitted by January 4, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise D. Dion, Office of Regulatory Affairs (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, FAX 301–443–6919.

SUPPLEMENTARY INFORMATION: During the FDA/medical device industry grassroots forums in 1995, several issues were discussed concerning FDA's interaction with the medical device industry. A decision was made to consider action on three of the issues discussed. These included instituting: (1) Preannounced inspections, (2) listing promised or completed corrective actions on FDA–483 items, and (3) postinspection notification to establishments regarding their compliance status.

After considering these issues, the agency decided to initiate a pilot program involving the medical device industry in fiscal year (FY) 1996. The pilot program occurred during the 1996 calendar year and was then formally evaluated. The pilot program included criteria and procedures for preannounced inspections, the annotation of FDA–483 items with promised or completed corrections, and postinspection correspondence.

The program was restricted to inspections of medical device manufacturers that manufactured only medical device products, and it did not include manufacturers of products that cross different program areas like devices/drugs/biologics.

Although the pilot program did not include those inspections performed under State contract for FDA, the contracts were modified after permanent adoption of the Medical Device Initiatives.

Implementation of the program was not shown to decrease the level of necessary enforcement. Previous FDA experience had indicated that the overall out-of-compliance rate for preannounced foreign inspections was comparable to, or even greater than, the overall out-of-compliance rate for domestic inspections where preannouncements generally were not made.

Preannounced inspections were offered to those medical device firms that met the criteria for inclusion in the pilot program. FDA–483 annotations and the postinspection notification were done for all medical device inspections. The annotations and the notifications were independent of whether the inspection was preannounced.

The purpose of the pilot program was to optimize resource utilization, enhance FDA/industry communication, and provide firms prompt closure to corrected inspection observations and nonviolative inspections, and inspections in which voluntary action only is indicated.

There were 1,034 domestic medical device inspections (excluding bioresearch monitoring inspections) conducted during the pilot program. FDA received 432 completed industry feedback questionnaires and summary questionnaire data from FDA investigators for all 1,034.

The investigators' questionnaire data showed that 844 (or 81 percent) of the inspections were preannounced (the others were either not eligible for preannouncement or were begun prior to April 3, 1996, the start of the pilot program). Of those that were preannounced, 69 percent had inspection time savings due to preannouncement. Investigators reported that 83 percent of those preannounced inspections were facilitated by the preannouncement for the following reasons: Inspections had quicker startups; inspections had records more readily available; and inspections had personnel more readily available.

Investigators reported that 443 FDA–483's, Inspection Observations, were issued during this pilot program. The investigators reported that during 83 percent of the inspections, they were notified by the firm of corrections made during the inspection. Investigators reported that during 78 percent of the inspections, the time spent to annotate the FDA–483's was worthwhile.

Of the 1,034 inspections conducted under this pilot program, 893 (or 89 percent) of the inspections were classified ''no action indicated'' (NAI) or ''voluntary action indicated'' (VAI). Seven-hundred sixty-nine (or 86 percent of the 893 NAI/VAI inspections) postinspection letters were issued by the end of the pilot program period, December 31, 1997. Due to a time lag between conclusion of the inspection and issuance of the letters, additional letters were sent but not reported as part of the pilot evaluation.

The industry's questionnaire data indicated that in 90 percent of the inspections that were preannounced, the preannouncements were helpful to the firms in preparing for the inspection. Industry responded that during 93 percent of the inspections, the firm's personnel were notified during the inspection of noncompliances found by the inspection team and that in 86 percent of the inspections, the firms notified the FDA inspection team of corrective actions. In 78 percent of the inspections, the FDA inspection team was able to verify that corrective actions had been made.

The industry respondents reported that 95 percent of them felt that the FDA–483 annotations were appropriate and 94 percent felt that they were helpful. Ninety-five percent of the respondents found the postinspection letters helpful and 95 percent of the respondents felt the pilot program helped to increase the spirit of cooperation between their establishment and FDA.

Twenty-one of the investigator responses stated that the preannouncements compromised the inspection process. Further evaluation of these 21 responses revealed that 19 of the respondents had misunderstood and thus inaccurately answered this question. The remaining two have been evaluated and FDA has concluded that the problems described by these investigators do not warrant discontinuing the program. Because of the positive findings of the evaluation, the program was formally adopted as the Medical Device Initiatives program in FY 1997. The elements of the Medical Device Industry Initiatives Program are described in Attachment A of a new inspection guide entitled ''Guide to Inspections of Medical Device Manufacturers,'' dated December 1997 and posted to FDA's World Wide Website at ''www.fda.gov/ora''.

With some industry-specific caveats, FDA is prepared to begin another yearlong pilot program of the initiatives to provide similar coverage to the other program areas, including drugs (both human and animal) and biologics. Only FDA–483 annotation and postinspection notification will be piloted in the foods program area. Upon completion of the pilot program, FDA will perform an evaluation to evaluate the effectiveness in optimizing resources, enhancing FDA/industry communication, and providing firms prompt closure to corrected inspection observations and nonviolative inspections, or inspections in which voluntary action only is indicated. In addition, the impact on violative situations will be evaluated.

The elements of the agency initiatives are as follows:

I. Preannounced Inspections

A. Basic Premises

1. Preannouncement of inspections is intended to be applied only to those drug, medical device and biologics, except for blood and plasma collection and processing firms, that meet the criteria for consideration. Preannouncement of inspections is not applicable for manufacturers of or other operators dealing in only food, blood or plasma product commodities.

2. The eligibility of an individual firm for preannounced inspection is at the discretion of the inspecting office using clearly described criteria. (See section I.B of this document.)

3. The implementation of this preannounced inspection program is intended to be flexible, based on appropriate considerations of the agency and the firm.

4. The preannouncement should generally be no less than 5 calendar days in advance of the inspection. Should a postponement be necessary, the decision as to the time of rescheduling rests with the investigator/team, but the new inspection date should not be later than 5 calendar days from the originally set date. Inspections may be conducted sooner than 5 calendar days if requested by the firm and if this date is acceptable to the investigator/team.

5. To participate in the preannouncement portion of the program, firms are expected to meet the commitment to have appropriate records and personnel available during the inspection.

6. Preannounced inspections will not limit an investigator's authority to conduct the inspection. Inspections will be as in depth as necessary.

B. Criteria for Consideration

The criteria to be used by the inspecting office to determine whether it is appropriate to preannounce a planned inspection will include:

1. Type of Inspection:

a. Premarket inspections (PMA, NDA, prelicense, etc.),

b. Foreign inspections,

c. Bioresearch monitoring inspections,

d. Quality system (QS) or good manufacturing practice (GMP) inspections:

Biennial routine inspections,

Initial inspections of newly registered establishments,

Initial inspections of new facilities, and

Initial inspections under new management and/or ownership.

e. Non-QS/GMP inspections other than:

Government Wide Quality Assurance (GWQAP) inspections with short deadlines,

Immediate and urgent responses to complaints,

Immediate and urgent followup to information from any source, and

Immediate hazard to health recall followup inspections.

f. Recall followup inspections at manufacturers/initial importers/U.S. designated agent.

2. Eligibility Criteria:

a. GMP inspections of firms with nonviolative histories (inspections classified as no action indicated (NAI) or voluntary action indicated (VAI)). For VAI, adequate corrections of conditions observed and listed on FDA–483 during the previous inspection were verified and did not lead to any further agency action.

b. To remain eligible for preannounced inspections, firms must have a history of having individuals and/or documents identified in previous preannounced inspections reasonably available at the time of inspection.

C. Procedures

1. The investigator or coordination group designated to conduct the inspection will contact or, if unavailable at the time of call, leave word for the most responsible individual at the facility.

2. Changes in dates should be kept to a minimum. If a change is made, a new date should be provided as soon as possible that will facilitate the inspection and accommodate the investigator's schedule.

3. Preannouncements are normally limited to the investigator (or lead investigator or coordinating group for a team inspection) informing the firm of an upcoming inspection. Usually it will be appropriate to inform the firm as to the purpose, estimated duration, and the number of agency personnel expected to take part in the inspection. The products or processes to be covered should also be described if this will facilitate and be consistent with the objectives of the inspection.

4. When known, specific records/personnel will be requested at the time the inspection is scheduled.

II. FDA–483 Annotations

A. Basic Premise

1. For inspections in all program areas, the investigator will annotate the FDA–483 at the time of issuance to acknowledge an establishment's promised or completed corrective action. The firm should review the annotations on this issued FDA–483 to ensure that there are no misunderstandings about promised corrective actions.

2. A reportable item will not be deleted from the FDA–483 because the establishment has promised or completed a corrective action. The investigator will continue to have the latitude to delete the observation if the establishment's response to the observation clearly shows that the observation is in error or to clarify the observation based on additional information provided.

3. FDA investigators will continue to report only significant observations on the FDA–483 and to discuss these and other less significant observations with the establishment's management.

B. Procedures

1. Investigators and analysts will discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when the FDA–483 is issued. This discussion will include those observations that may be written on the FDA–483 and oral observations. Industry should use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made as soon as possible during the inspection. Investigators are encouraged to verify the establishment's completed corrective actions as long as the verification does not unreasonably extend the duration of the inspection.

2. Where practical, FDA–483 observations should include the number of records of a given type examined, for example, ''Two out of 50 records examined were * * *.''

3. If the establishment has promised and/or completed a corrective action to an FDA–483 observation prior to the completion of the inspection, all copies of the FDA–483 should be annotated (either following each observation or at the end of the FDA–483) with one or more of the following comments, as appropriate:

Item # _____ reported corrected but not verified.

Item # _____ corrected and verified.

Correction of items_____, _____ and promised by 00/00/98.

No comment at this time.

4. If an observation made during a prior inspection is noted as not being corrected or is a reoccurring observation, it is appropriate to note this on the FDA–483.

5. All corrective action taken by the establishment and verified by FDA should be discussed in detail in the establishment inspection report and reported using the Compliance Achievement Reporting Systems (CARS).

III. Postinspection Notification

A. Basic Premise

1. FDA will issue postinspection notification to establishments regarding their compliance status for all inspections except foreign drug establishments. Foreign drug establishments have traditionally and will continue to receive correspondence from FDA upon evaluation and closure of each inspection.

2. The two new categories under which firms will receive postinspection notification are:

a. NAI situations where no FDA–483 was issued or only limited, less significant deficiencies were reported.

b. VAI situations where an FDA–483 was issued but all profile classes were found acceptable. In this circumstance, no further action is contemplated based on the inspection.

3. The postinspection notification letters that are issued under this pilot program will be mailed under the signature of the district director, in that district in which the establishment is located, or the Director of the Center of Compliance, as appropriate.

4. For those inspections where further action is being considered, FDA's existing modes of notification will continue to be used.

Dated: November 5, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30608 Filed 11–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0335]

Agency Information Collection Activities; Announcement of OMB Approval; Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled '' Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 25, 1998 (63 FR 51357), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0119. The approval expires on October 31, 2001.