TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
610.40(b) [2]	1	1	0.5	0.5	
610.40(d) [3]	12	1.83	22	0.5	11
Total					11.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] The notice involves a brief letter and an enclosure. The letter identifies who is making the shipment, to whom shipped, the nature of the emergency, the kind and quantity shipped, and date of shipment. The enclosure is a copy of the shippers written standard operating procedures for handling, labeling storage, and shipment of contaminated (contagious) product. The burden for development and maintenance of standard operating procedures is approved under OMB No. 0910–0116.

[3] The notice of reactive product shipment is limited to information on: The identity of the kind and amount of source material shipped; the name and address of the consignee; the date of shipment; and the manner in which the source material is labeled.

FDA has calculated no additional burden in this information collection package for the labeling requirements in § 610.40(d) because the information and statements on the label necessary for public disclosure and safety are provided by FDA in these regulations. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: August, 30 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–22951 Filed 9–6–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0836]

Agency Information Collection Activities; Announcement of OMB Approval; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Environmental Impact Considerations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the**Federal Register** of March, 13, 2000 (65 FR 13405), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 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 0910–0322. The approval expires on August, 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–22849 Filed 9–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N 0928]

Agency Information Collection Activities; Announcement of OMB Approval; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Request for Samples and Protocols'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 July 6, 2000 (65 FR 41678), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 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 0206. The approval expires on August 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–22850 Filed 9–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1439]

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 December 6, 2000.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

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., 16 Forest Rd., suite 200, P.O. Box 8251, St. John's, Newfoundland, Canada, A1B 3N4.

The permit covers limited interstate marketing tests of products identified as ''iceberg water'' that deviate 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 150,000 cases of the 24 x 350 milliliters (ml), 150,000 cases of the 12 x 1 liters (L), and another 100,000 cases of the 24 x 500 ml giving 400,000 cases in total. The total fluid weight of the test product will be 1,124,024 gallons or 4,260,000 L). The test product will be manufactured at Iceberg Industries Corp. Water Bottling Plant, Daniel's Point, Trepassy, Newfoundland, Canada, A0A 4B0. The product will be distributed by Iceberg Industries in 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 December 6, 2000.

Dated: August 23, 2000.

Christine J. Lewis,

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

[FR Doc. 00–22950 Filed 9–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: AIDS Drug Assistance Program (ADAP): ADAP Monthly Client Utilization and Program Expenditures Report (OMB No. 0915–0219)—Revision

State AIDS Drug Assistance Programs (ADAPs), funded under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996 (Pub. L. 104–146), are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medications that prevent serious deterioration of health arising from HIV disease, including the prevention and treatment of opportunistic infections.

During the last several years, there has been an increasing need for pharmaceuticals among uninsured and underinsured low-income individuals who are HIV positive or diagnosed with AIDS. Due to the increasing demand, the Division of Service Systems (DSS), Health Resources and Services Administration (HRSA) recognizes the importance of program planning and budget forecasting in order to maximize resources, and proposes to revise the current data collection form to better collect relevant client utilization data and program expenditure information from State ADAPs. This data collection effort is designed to allow DSS/HRSA (the funding agency) to monitor nationwide trends in program growth, client utilization, expenditures and to assess the capacity of State ADAPs to maintain services for clients throughout the fiscal year. The revised form will improve DSS/HRSA's ability to track the prices of HIV/AIDS drugs in order to ensure that State ADAPs are receiving the best price possible, to identify emerging issues and technical assistance needs, and to share information among State ADAPs. It will also assist Title II grantees, State ADAPs, DSS/HRSA staff, and policymakers at both the Federal and State level to better understand the level of client demand for medications and the resources needed to meet those needs.

The revised report will collect time-specific data for the number of enrolled clients, the number of new clients, the number of utilizing clients, the level of funds expended, and the price of HIV/AIDS drugs. A text box is provided to allow State ADAPs to report significant changes to their program, such as a projected budget shortfall, program restrictions, client waiting lists, a change in eligibility criteria, or formulary changes. On a quarterly basis, State ADAPs will report the purchase price paid on a select number of HIV pharmaceuticals dispensed by each program. DSS/HRSA will continue to compile summary reports that are distributed back to grantees and State ADAPs on a quarterly basis. The data collected is used to guide program planning, formulate budget recommendations, and monitor State ADAPs, especially monitoring the balance between an individual State ADAP's available resources against the client demand for medications. The burden estimates are as follows:

HRSA form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Title II ADAP Grantees (Clients and Expenditures)	54	12	648	0.75	486
Title II ADAP Grantees (Pricing)	54	4	216	0.75	162