

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section         | No. of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 610.40(b) <sup>2</sup> | 1                  | 1                             | 0.5                    | 0.5                | 11          |
| 610.40(d) <sup>3</sup> | 12                 | 1.83                          | 22                     | 0.5                | 11.5        |
| Total                  |                    |                               |                        |                    |             |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> 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.

<sup>3</sup> 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.*

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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.*

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## 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.*

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## 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.