



INTERNATIONAL  
BOTTLED WATER  
ASSOCIATION

7971 '01 SEP 17 P1248

September 14, 2001

*BY HAND DELIVERY*

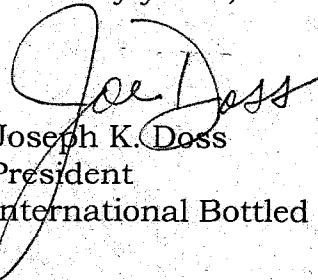
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

**Re: Citizen Petition**

Dear Sir or Madam:

On behalf of the International Bottled Water Association, I am filing the attached Citizen Petition. Consistent with 21 C.F.R. § 10.20(a), I am filing the original and three copies. Thank you for your assistance in this matter.

Sincerely yours,



Joseph K. Doss  
President  
International Bottled Water Association

Attachment

01P.0406

CP1





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Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20857

### **Citizen Petition**

The International Bottled Water Association (IBWA) is the trade association representing the bottled water industry. Founded in 1958, IBWA member companies account for more than 80 percent of all bottled water sales in the U.S. IBWA's membership includes U.S. and international bottlers, distributors and suppliers. IBWA is committed to working with state and federal governments, in concert with the IBWA Model Code, to set stringent bottled water standards for safe, high quality products.

As producers of a packaged food product, bottled water companies must comply with FDA's longstanding labeling requirements for conventional foods. These requirements include providing a statement of identity, a manufacturer/distributor identification, and nutrition information (when nutritional claims are made or nutrients are added) on the product label. In addition, bottled water producers must comply with FDA's standards of identity and quality for these products.

The standard of quality involves testing the water source and finished product for a variety of contaminants. As a result of these monitoring and testing requirements, bottled water manufacturers have a great deal of information about the content of their products. As responsible manufacturers, they also possess detailed information about the source of their water, the processing it undergoes, and other areas of interest to consumers.

On August 6, 1996, the Safe Drinking Water Act Amendments (SDWA) became law. Pub. L. No. 104-182, 110 Stat. 1613. Section 114 of the SDWA required the Environmental Protection Agency (EPA) to issue regulations mandating that each community water system mail to customers of the system an annual report regarding the level of contaminants in the drinking water purveyed by that system. EPA issued a final rule requiring local water systems to provide such contaminant information by way of a "consumer confidence report" (CCR) mailed to customers on an annual basis. 63 Fed. Reg. 44511 (Aug. 19, 1998).

The SDWA also directed the Food and Drug Administration (FDA) to prepare a study of the feasibility of appropriate methods, if any, of informing customers of the bottled water industry of the contents of bottled water. FDA published a final study report, *Feasibility of Appropriate Methods of Informing*

*Customers of the Contents of Bottled Water*, on August 25, 2000. 65 Fed. Reg. 51833 (Aug. 25, 2000). The agency concluded that it would be feasible for producers of bottled water to make available the type of information contained in a CCR through provision of a company contact phone number on the product label. *Id.* at 51836.

IBWA submits this petition to request that FDA amend 21 C.F.R. § 101.5 ("Food; name and place of business of manufacturer, packer, or distributor") to require that the label for bottled water products subject to the standard of identity for bottled water at 21 C.F.R. § 165.110 include a company contact telephone number. The contact number would provide consumers with a quick, efficient means of obtaining a variety of information about the bottled water products they consume, including applicable and relevant CCR-type information. Such action would also be consistent with the IBWA Model Code which, effective January 1, 2002, will require IBWA members' proprietary brands of bottled water to display a telephone contact number on the product label. As of that date, IBWA's Model Code will also recommend, but not require, that this same information appear on the labels of private label brands produced by IBWA members.

#### **ACTION REQUESTED**

Petitioners hereby respectfully request that FDA amend 21 C.F.R. § 101.5 to add the following new paragraph:

(f) In addition to the information required by this section, the label of any bottled water subject to § 165.110 shall bear a telephone number that consumers may call to obtain information.

#### **STATEMENT OF GROUNDS**

At its June 2001 meeting, the Board of Directors of IBWA voted to amend IBWA's Model Code effective January 1, 2002 to require IBWA members to include a company contact telephone number on the label of proprietary brands of bottled water produced by IBWA member companies. As of that date, the Model Code will also recommend but not require that a company contact number appear on the labels of private label brands of bottled water. The company contact number is intended to assist consumers who wish to obtain additional information about the products. Specifically, Rule 6(d) of the IBWA Model Code now reads:

In addition to the label information required under 21 CFR Sections 101.5 and 165.110 and 21 USC Section 343, IBWA member proprietary brands must also include on the label a telephone number of the bottler, distributor or brand owner as a

means of contact for consumers who wish to obtain additional product information. It is strongly recommended that private label brands produced by IBWA members include the telephone number of the bottler, distributor or brand owner.

Although IBWA represents a very large portion of the bottled water industry, its membership does not encompass all bottled water manufacturers. This petition is intended, therefore, to extend the provisions of Rule 6(d) of IBWA's Model Code to all bottled water manufacturers.

Bottled water producers are extensively regulated by FDA and are required to monitor and test for numerous microbiological, physical, and chemical contaminants. In addition to complying with the standard of identity for bottled water in 21 C.F.R. § 165.110(a), bottled water manufacturers must ensure that their product satisfies FDA's standard of quality for bottled water at 21 C.F.R. § 165.110(b).

The standard of quality sets allowable levels for 95 microbiological, chemical and radiological contaminants in bottled water. To ensure compliance with those allowable levels, and in accordance with the bottled water Good Manufacturing Practices (GMPs) described more fully below, bottled water producers must sample both their source and product water in accordance with a schedule mandated by FDA. If a bottled water product contains an amount of any of these substances that exceeds the particular standard of quality level, the product is misbranded unless the label states that the product "contains excessive \_\_\_\_." Further the presence of the substance may cause the product to be adulterated if the level present is such that it may be injurious to health.

In addition to satisfying the above-referenced standard of quality, bottled water producers must operate in accordance with the bottled water GMPs, one of the few segment-specific GMP regulations for the food industry. The bottled water GMPs establish standards for the collection, processing, and packaging of bottled water in a manner that is safe and sanitary. Importantly, these regulations mandate testing of both source and product water to assure compliance with FDA and/or other relevant governmental standards.

Specifically with regard to source water, the GMPs require that source water be taken "from an approved source properly located, protected and operated" and that the source "be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction." 21 C.F.R. § 129.35(a)(1). These agencies are typically the relevant state government entities. In addition, the GMPs mandate that samples of source water are to be taken "as often as necessary . . . but not less than weekly for microbiological contaminants." 21 C.F.R. § 129.35(a)(3). Further, bottled water producers must "for bacteriological purposes, take and

identity for bottled water at 21 C.F.R. § 165.110 bear a telephone number on the product label.

### **ENVIRONMENTAL IMPACT**

The action requested by the petition is subject to categorical exclusion under 21 C.F.R. § 25.30(k) because it would establish a labeling requirement and would not increase existing levels of use of bottled water or change the intended use of bottled water. Accordingly, preparation of an environmental assessment or an environmental impact statement is not required.

### **ECONOMIC IMPACT**

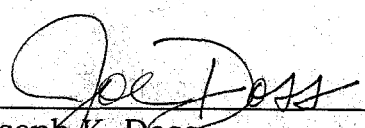
An economic impact statement under 21 C.F.R. § 10.30(b) is not required at this time.

\* \* \* \* \*

The undersigned certifies that, to the best of its knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

International Bottled Water Association

  
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