



INTERNATIONAL  
BOTTLED WATER  
ASSOCIATION

5073 '00 APR 24 P4:01

April 24, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 97N-0436 / FDA Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

Dear Sir/Madam:

The International Bottled Water Association ("IBWA") appreciates the opportunity to submit comments to the Food and Drug Administration ("FDA" or "Agency") on the February 22, 2000 FDA Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water ("Draft Study Report"). IBWA is the trade association representing all segments of the bottled water industry. Our member companies produce and distribute approximately 85% of the bottled water sold in the United States. The association membership includes more than 1500 domestic and international bottlers, distributors and suppliers.

IBWA believes that consumers should be able to obtain information about the safety and quality of bottled water on a timely basis. Indeed, consumers now can readily obtain that information upon a simple request. FDA labeling requirements mandate that the name and place of business of the manufacturer, packer or distributor appear on the label. Further, IBWA members must comply with the association's Model Code which calls for providing a telephone number on the label. This allows consumers easy access to the information if they wish to have it.

While the draft study report is intended to evaluate the feasibility of communicating information on the contents of bottled water, FDA acknowledged that to do so it must consider the type and amount of information to be conveyed as well. In doing so, FDA must continue to keep squarely in mind the fact that bottled water is a packaged food regulated like all other packaged foods under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321, et. seq.) ("the Act") while municipal water systems which convey water in nonpackaged, continuous distribution systems, are regulated very differently under the Safe Drinking Water Act (42 U.S.C. § 300f et. seq.) ("SDWA"). While the distribution of a Consumer Confidence Report ("CCR") under the SDWA may be appropriate under that statutory scheme, it is not, as set forth below, either necessary, since it is easily available, nor legally required under the extensive regulatory system for packaged foods under the Act.

**I. There Are Vastly Different Regulatory Programs For Bottled Water Versus Municipal Water Systems**

We are pleased that the Agency realizes there are distinct differences between bottled water and municipal water systems. It is critically important to continue to recognize the dramatic regulatory differences between bottled water and municipal water.

97N-0436

C 65



- Bottled water is a packaged food regulated by FDA in the same way it regulates all other packaged beverages and other foods.
- Bottled water is subject to the food labeling requirements of the Act (21 U.S.C. § 343).
- Bottled water is subject to the food adulteration requirements of the Act (21 U.S.C. § 342).
- As a packaged food, bottled water is subject to the full panoply of FDA enforcement actions, including Warning Letters, recalls, civil (seizure and/or injunction) and criminal penalties. (21 U.S.C. § 331-337.)
- Bottled water has its own unique set of bottled water Good Manufacturing Practice regulations (21 C.F.R. § 129.1 et. seq.) in addition to being subject to the general Food Good Manufacturing Practice regulations. (21 C.F.R. § 110.3 et. seq.)
- Bottled water has an extensive Standard of Identity regulation that defines products such as spring water, purified water, and drinking water. (21 C.F.R. § 1165.110(a).) If a product calls itself "spring water" and does not meet the FDA definition in the Standard of Identity, it is misbranded and subject to civil and/or criminal enforcement action.
- Bottled water has 83 "allowable levels" for various contaminants set forth in the Standard of Quality. (21 C.F.R. § 165.110(b).) If a bottled water product, which must be tested for compliance with these allowable limits, contains a contaminant at a level above the "allowable level", it must be labeled "contains excessive \_\_\_\_\_" or it is a misbranded food product subject to civil or criminal enforcement action. (21 U.S.C. § 343(h).)
- If the level of a contaminant is such that it may be injurious to health, the bottled water product may be adulterated and subject to the civil and/or criminal enforcement action identified above.

FDA has also recognized that its legal authority to require CCR information either on or off-label was not addressed by SDWA (65 FR at 8718). That is correct. Presently, all packaged foods, including bottled water, have extensive labeling requirements, including a statement of identity, compliance with the definitions in the Standard of Identity, ingredient labeling, name and place of business of the manufacturer, packer or distributor and nutrition labeling, if otherwise required. Any other information FDA may wish to require by regulation must be considered a material fact, the absence of which will result in misleading labeling for failure to reveal a material fact. (21 U.S.C. § 321(n); 21 U.S.C. § 343(a).) FDA, including its present Commissioner, has consistently said regulations such as this must be based on solid science. Thus, it is not surprising that, except for several safety warnings, FDA has never promulgated a regulation requiring additional information on food labeling. Other information about a product that does not rise to the FDA standard for a material fact may not be required.

In stark contrast to the regulatory system for a packaged food, EPA regulates municipal water through the establishment of Maximum Containment Levels and a program for municipal water companies to monitor these levels under the SDWA. Since the water is conveyed to consumers through a distribution system that does not allow for product recall or other product removal, information to the public about the quality of municipal water is appropriate. A Consumer Confidence Report makes sense in such a distribution system. It does not make sense for packaged foods such as bottled water.

When discussing the contents of bottled water, the Draft Study Report states:

*"We realize that not all of the information in a CCR is relevant to bottled water. For example, FDA establishes "allowable levels" for contaminants, not MCLs (FDA has established allowable levels for 83 contaminants in bottled water)." (65 Fed. Reg. 8719)*

In analyzing the six key elements of an EPA CCR identified by FDA, it becomes very apparent that few of those elements are applicable to bottled water, and none would be viewed as material facts for purposes of required labeling. Specifically:

1. Source of drinking water - FDA concluded in the preamble to the Standard of Identity Final Rule that this information was not material and, therefore, not required to appear on a bottled water label. (60 Fed. Reg. 57076, 57096)
2. Definitions of maximum contaminant level ("MCL") and maximum contaminant level goal ("MCLG") – As previously stated, FDA recognized that these terms are not relevant to bottled water.
3. MCL, MCLG, and the contaminant level detected in the water and any contaminant level that violates an MCL and the health effects information - This information is also irrelevant to bottled water. As set forth above, if a bottled water product is violative of a contaminant for which there is a FDA "Standard of Quality" allowable level, the product must be labeled to reflect this substandard level of quality (e.g., "contains excessive \_\_\_\_\_"). 21 C.F.R. § 165.110(c), 21 U.S.C. § 343(h)(1). Further, and most importantly, to the extent that a bottled water product contains a contaminant above the Standard of Quality allowable level and it may be injurious to health, such product is adulterated. The product is subject to FDA enforcement action if the product is misbranded or adulterated. EPA's enforcement action for water utilities that violate an MCL (public health standard) is not based on the same principles as FDA.
4. Compliance information and whether the system operates under a variance or exemption - FDA specifically recognized that systems operating under a variance or exemption is relevant only to public water systems. We agree with FDA's conclusion.
5. Information on the levels of unregulated contaminants for which monitoring is required, such as *Cryptosporidium* and radon – FDA does not require bottled water or any other food product to monitor for "unregulated contaminants." To the extent there is a contaminant that causes a bottled water product to be adulterated under the Act, there are far more effective enforcement tools available to FDA. This is not a relevant provision for bottled water.
6. The statement that the presence of contaminants in drinking water does not necessarily pose a health risk and consumers can obtain more information by calling the EPA Hotline - This statement is not a material fact under Section 321(n) of the Act. FDA specifically recognized that EPA's drinking water hotline is relevant only to public water systems. Such a statement is obviously irrelevant to bottled water.

IBWA and its members do not dispute the public's right to obtain information about the safety of all food products including bottled water. However, given the existing labeling regulations to which bottled water products are subject and ease of obtaining detailed product analyses and product quality information from bottled water companies, a mandate by the Agency for disseminating product information through new regulations is unnecessary. We believe additional regulations for an industry that voluntarily shares comprehensive information about its products with all consumers, simply are not necessary.

While we understand the draft study report is required under the 1996 Safe Drinking Water Act (SDWA) amendments, it is inappropriate to single out one food product for possible additional consumer information requirements when there is no public health or public policy basis. Indeed, many foods contain water as a

primary ingredient, including soft drinks, juices, bottled teas and canned vegetables. These foods are not required to provide label information similar to that provided in a CCR. The current FDA regulations ensure the continued safety and quality of all packaged foods, including bottled water, from manufacturing to packaging to distribution.

Consumers are empowered by the choices they are able to make in a free market economy. With the information currently required to be on the bottled water label, consumers are easily able to contact the manufacturer to obtain more information to assist them in making an informed decision on the bottled water product they wish to purchase. However, consumers have no choice in the municipal water systems that serve their homes and communities regardless of the amount of solicited or unsolicited information they may receive.

Since we believe the current product labeling requirements are more than adequate to ensure a means of relaying information to the customer, the Agency should only recommend voluntary options for the manufacturer, not mandates.

## **II. Specific Comments On Possible Methods Of Communication Identified By FDA**

We have reviewed the six methods evaluated in the February 22, 2000 Federal Register Notice and offer the following comments related to their feasibility, costs and other pertinent factors. While we will discuss the "feasibility" of such methods, our discussion does not suggest or agree that we believe such information either on or off-label should be required by FDA nor would FDA have the legal authority to do so without a solid scientific basis.

### **A. Additional Information On The Label Beyond What Is Already Provided Is Not An Appropriate Method For Providing Consumers About Product Information**

We agree with FDA's determination that "*placing all of the information analogous to that contained in a CCR on the label is not feasible.*" (65 Fed. Reg. 8722). Furthermore, we agree with the Agency's concerns with the economic feasibility of placing certain information on the label:

*"Labeling changes for information that may change frequently could result in an economic hardship to companies and, in addition, would result in the possibility that a product might bear a label that was no longer accurate, due to changing test results, which may cause the product to be misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act."* (21 U. S. C. § 343). (65 FR 8720)

The bottled water label is not the appropriate means to disseminate information analogous to that required by a CCR. The label's size and the frequency of product testing prohibit the use of the label as the most expedient means of distributing comprehensive bottled water product information. Contacting the bottler will provide a more thorough and timely means for consumers to obtain information about bottled water quality and safety.

The costs associated with frequent label changes would be substantial. We appreciate that FDA recognizes label costs would be impacted by the complexity of the label change, the number of labels a company uses, and the time parameters for implementing the multiple label changes in response to changing test results.

### **B. Information Available By Company Contact Is Currently Provided On The Label**

We agree with FDA's evaluation that "*a phone number or address on the label directing customers on how to obtain information from the company is an appropriate method of providing information to customers.*" (65 FR 8720)

The public's right to information regarding food products they consume is indisputable. In recognition of this, IBWA's members make available to any consumer, upon request, a report of their product's annual analysis for contaminants listed in the IBWA Model Code, which covers all FDA requirements plus many additional contaminants and other pertinent information. This information is currently acquired by the consumer through request by telephone or letter, member web sites, or through publication of information in a company's marketing materials.

In a letter to Dr. Jane Henney dated July 14, 1999, in response to the Natural Resource Defense Council's citizen petition, IBWA stated that "the current means of informing consumers about the contents of bottled water, such as providing detailed product and multi-barrier information on web sites, contact information on product labels, and direct consumer requests for the information from bottlers, meet the standard, are effective, and are appropriate." Although most IBWA members presently provide a telephone number on the label, and many actually already provide a toll-free telephone number, we disagree with a toll-free (i.e., 800 or 888) telephone number requirement. This would also be incredibly burdensome on some bottled water companies without significant benefit to the consumer. For example, a toll-free telephone number would be very costly for some small bottled water companies that serve a limited geographic area. Furthermore, use of a toll-free telephone contact number is not currently required of food processors for any other packaged food commodities.

**C. *Information Available By The Combination Approach Is Not Necessary As Appropriate Company Contact Information Is Already Provided On The Label***

We have concerns with the Agency's evaluation of the combination approach as an appropriate method of providing information to customers. Customers already have company contact information available at point of purchase, as required by law (e.g., name and address of the manufacturer, packer or distributor). As previously stated, customers can then contact the company for specific product information. This current system works. Providing some additional information on the label (e.g., treatment, source) should be voluntary. It is inappropriate to mandate any additional labeling for one single food product when there is no public health or public policy basis.

The source and treatment are not material facts under the Act as discussed above. Therefore, this information does not need to be included on the bottled water product label.

**D. *Information In A Pamphlet Is Not The Most Feasible Method Of Providing Information To Customers***

We agree with FDA's evaluation of pamphlets as presented in the draft feasibility study report, which states:

*"Therefore, we do not believe that pamphlets would be the most feasible method of providing information on the contents of bottled water to customers." (65 FR 8721)*

Store stock managers will not oversee this and substantial costs will be incurred by the bottler to hire personnel to ensure pamphlets are in place at retail. Ensuring pamphlets are in stock does not come under the purview of the industry's distributors or brokers.

Given the number of retail facilities encountered by our member bottlers, the cost of printing and maintaining supplies of pamphlets is ten times the FDA's conservative estimates.

As with labels, pamphlets are expensive to prepare, and water quality information is subject to change, therefore making a pamphlet a costly method of reporting water quality information to consumers. The current method of reporting to customers upon request permits timely updates of information.

**E. *Distribution Of An Information Package With Bulk Water Deliveries Is Practical When Requested By The Customer***

While we recognize the feasibility of this method, we disagree with FDA's suggested frequency to deliver this information with an invoice and that "bulk water deliverers" have regular contact with their customers.

Bulk water deliverers may not have regular contact with their customers. In California alone, one IBWA member bottler has over 600,000 home and office customers who receive 3 and 5-gallon containers at least every two weeks. Clearly, more than 20 "bulk deliveries" a week are made in order to service this particular customer base. Deliveries to home and office do not ensure that the company's route sales representatives will encounter any one at the account location at the time of delivery. Therefore, we do not support leaving product information with every delivery as this would be overkill and very expensive to print and reprint "information packets."

Having the customer contact the bottler via the information on the cap label of home and office products (3 or 5 gallon) is preferable. FDA recognized the concept - if the consumer wants the information, they will ask for it when it stated:

*"The information also could be provided to customers by bulk deliverers only in response to customer request. This would reduce the chance for customers who are not seeking additional information on the contents of bottled water to be confused by information that may not be relevant to them or in which they have no interest." (65 FR 8721)*

This is a key comment made by the Agency. We feel that this comment is applicable not only for home and office products, but also for products sold at retail.

If the customer wants the information, bottled water companies currently provide the contact information needed and required by law on all product labels to reach the company and receive the information they seek in a timely manner.

Using the Agency's conservative cost estimates, the IBWA member bottler discussed above would spend on an annual basis \$600,000.00 to \$1,200,000.00 to produce and distribute "informal information packets."

Clarification is also needed on the Agency's perspective of what a bulk water delivery entails. Is the Agency referring to water haulers who deliver tankers of water to manufacturing/bottling facilities or home/office delivery (e.g., 3 or 5 gallon)?

**F. *Information Available On The Internet Is Useful, But Should Not Be A Primary Means Of Providing Information To Customers***

We agree with FDA's evaluation that:

*"The agency does not believe that the Internet may be appropriate as the sole method of providing information on the contents of bottled water to customers because not all customers may have access to it." (65 FR 8722)*

The Internet is another means by which consumers may obtain information about bottled water, where available. However, as FDA noted in their evaluation, not every consumer has access to the Internet, nor does every bottled water company have a web site.

We also believe that FDA significantly underestimated the costs to create and maintain an Internet web site by at least 1000 fold, according to information provided by our member companies.

\* \* \* \* \*

Thank you for the opportunity to comment. We would be pleased to discuss these comments with representatives of FDA. Please contact Cindy Yablonski or Bob Hirst at (703) 683-5213 if you have any questions concerning this matter.

Sincerely,

INTERNATIONAL BOTTLED WATER ASSOCIATION



Joseph K. Doss

President

JKD/m

- C: IBWA Board of Directors  
Cynthia Yablonski, IBWA  
Bob Hirst, IBWA  
David Dexter, IBWA  
Joe Findaro, MGN, Inc.  
Robert Brady, Hogan & Hartson L.L.P.

**IBWA**

INTERNATIONAL  
BOTTLED WATER  
ASSOCIATION



**IBWA**  
INTERNATIONAL BOTTLED  
WATER ASSOCIATION  
1700 DIAGONAL RD  
SUITE 650  
ALEXANDRIA, VA 22314

**TO**

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852