FDA

MEMORANDUM

THE WHITE HOUSE

WASHINGTON

May 9, 1983

MEMORANDUM FOR FRED F. FIELDING

FROM: JOHN G. ROBERTS

SUBJECT: Petition Before FDA to Regulate Bottled Water

William F. Deal of the International Bottled Water Association (IBWA) has written, requesting a meeting with you to enlist Administration support for the IBWA petition before the FDA to regulate bottled mineral water. Under current rules bottled water is subject to FDA quality standards but bottled mineral water is not.

The FDA is not an independent regulatory agency as such but rather a component of HHS. Nonetheless it does perform regulatory functions and accordingly neither our office nor any other member of the White House staff should intercede in this particular regulatory matter. I have drafted an appropriate reply to Deal noting that our office must decline to become involved.

Attachment

THE WHITE HOUSE

WASHINGTON

May 10, 1983

Dear Mr. Deal:

Thank you for your letter of April 18, 1983, describing the petition filed before the Food and Drug Administration by the International Bottled Water Association, seeking to establish standards for bottled mineral water. In that letter you requested an opportunity to meet to discuss the petition and to enlist the support of the Administration.

As a matter of general policy, members of the White House staff may not contact an agency that performs regulatory or adjudicative functions, such as the Food and Drug Administration, concerning a particular matter pending before that agency. The purpose of this policy is to preserve the independence and integrity of the regulatory and adjudicative processes. It would in this case be inappropriate for our office to become involved in the consideration of a particular petition pending before the FDA.

I trust you will understand the need for us to adopt this approach.

Sincerely,

Orig. signed by FFF

Fred F. Fielding
Counsel to the President

Mr. William F. Deal, CAE
Executive Vice President
International Bottled
Water Association
113 North Henry Street
Alexandria, Virginia 22314

FFF:JGR:aw 5/10/83

cc: FFFielding
JGRoberts
Subj.
Chron

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WASHINGTON

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ID # 137304 CU

FG022-10

WHITE HOUSE
CORRESPONDENCE TRACKING WORKSHEET

☐ O - OUTGOING
☐ H - INTERNAL
☐ I - INCOMING
Date Correspondence Received (YY/MM/DD) / /

Roberts

Name of Correspondent: William F. Deal

☐ **MI Mail Report** **User Codes:** (A) _____ (B) _____ (C) _____

Subject: International Bottled Water Association urges support for petition requiring FDA to establish new rules to regulate the manufacture and sale of bottled mineral water in manner similar to bottled water industry.

ROUTE TO:	ACTION		DISPOSITION		
Office/Agency (Staff Name)	Action Code	Tracking Date YY/MM/DD	Type of Response	Code	Completion Date YY/MM/DD
CU Holland	ORIGINATOR	83 04 20			/ /
	Referral Note:				
CUATI8	D	83 04 20		S	83 04 20
	Referral Note:				
		/ /			/ /
	Referral Note:				
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	Referral Note:				
		/ /			/ /
	Referral Note:				

ACTION CODES:
A - Appropriate Action
C - Comment/Recommendation
D - Draft Response
F - Furnish Fact Sheet to be used as Enclosure
I - Info Copy Only/No Action Necessary
R - Direct Reply w/Copy
S - For Signature
X - Interim Reply

DISPOSITION CODES:
A - Answered
B - Non-Special Referral
C - Completed
S - Suspended

FOR OUTGOING CORRESPONDENCE:
Type of Response = Initials of Signer
Code = "A"
Completion Date = Date of Outgoing

Comments: _____

Keep this worksheet attached to the original incoming letter.
Send all routing updates to Central Reference (Room 75, OEOB).
Always return completed correspondence record to Central Files.
Refer questions about the correspondence tracking system to Central Reference, ext. 2590.

5/81

INTERNATIONAL BOTTLED WATER ASSOCIATION

April 18, 1983

Honorable Fred F. Fielding
Counsel to the President
The White House
Washington, DC 20500

Dear Mr. Fielding:

As Executive Vice President of the International Bottled Water Association ("IBWA"), I am writing to urge your support for a petition submitted to the Food and Drug Administration ("FDA") by the IBWA on behalf of the U.S. bottled water industry last February 22nd. The petition, which is supported by the industry at large, would require the FDA to establish new rules to regulate the manufacture and sale of bottled mineral water in a manner similar to the regulation of the bottled water industry.

Under current regulations, bottled water is subject to quality standards established by FDA. Bottled mineral water, however, was excluded from the definition of bottled water in the FDA regulations and thus is not subject to the water quality standards imposed on the bottled water industry generally.

The IBWA petition, a copy of which is enclosed for your information, is intended to fill the "gap" in the FDA's regulatory scheme and to ensure that all bottled water--- including bottled mineral water-- meet minimum health and safety standards.

In addition, the IBWA petition is intended to reduce consumer confusion over the source of some bottled water products which utilize misleading labeling to imply that they are "natural" mineral waters when in fact they are not.

We wish to emphasize that this petition represents a broad consensus of the bottled mineral water industry. It is also based on substantial consultation with FDA staff, which has suggested the general approach embodied in the petition.

113 N. Henry Street · Alexandria, VA 22314 · (703) 683-5213

We would very much like to meet with you at your convenience to discuss this matter further and to enlist the support of this Administration. Please feel free to call me or our Washington counsel Tim Harker (457-1054) in order to make suitable arrangements.

Sincerely,

William F. Deal, CAE
Executive Vice President

WFD/ck
enclosure
c.c. Timothy L. Harker, Esq.

PETITION

TO ESTABLISH A COMMON OR USUAL NAME AND SAFETY STANDARDS FOR BOTTLED MINERAL WATER

Submitted to the
Food and Drug Administration
U.S. Department of Health and Human Services

By the

International Bottled Water Association
Washington, D.C.

February 22, 1983

Introduction

The International Bottled Water Association ("IBWA") represents the bottled water and bottled mineral water industry of the United States. The membership of IBWA includes both domestic producers and importers of bottled water. IBWA members produce, sell, and distribute bottled water in five gallon containers for home and office use, one gallon containers for distribution through supermarkets, and a variety of smaller package sizes distributed through supermarkets and restaurants.

The American public is greatly concerned about diet, the quality of public water supplies, and the availability of high quality alternatives both to the public drinking water supply and other traditional consumer beverages. As a result, bottled water and bottled mineral water have become important segments of the American diet. Indeed, over 600 million gallons of bottled water is now consumed annually in the U.S. by the 1 out of every 18 families that use bottled water daily. In certain areas 1 out of every 3 families consumes bottled water daily.

IBWA is concerned that the current regulatory framework for the bottled water industry is seriously deficient in that "bottled water" is subject to Food and Drug Administration ("FDA") standards of quality, while "mineral water" is not. The regulatory scheme is intended to ensure that the bottled water industry provides American consumers with safe and high quality drinking water. This deficiency in the regulatory scheme is compounded by FDA's

failure to define "mineral water", thus leaving the parameters and scope of federal regulation highly ambiguous. Finally, the lack of federal regulation over this important segment of the bottled water industry has also led to consumer confusion by allowing some bottled water companies to market their products as "natural" mineral waters derived from protected underground sources when in fact they are "processed" surface waters artificially impregnated with manufactured mineral solids.

Accordingly, IBWA hereby submits this petition pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA" or "Act"), 21 U.S.C. § 301 et seq., and requests that the Commissioner of Food and Drugs ("Commissioner") issue regulations which (1) establish a common or usual name for "bottled mineral water," defined as any bottled water containing at least 500 ppm of naturally impregnated mineral solids and derived from an underground source; (2) establish a common or usual name for "bottled light mineral water," defined as any bottled water containing more than 250 ppm, but less than 500 ppm of naturally impregnated mineral solids and derived from an underground source; (3) set safety standards for bottled mineral water and bottled light mineral water which are based on the quality standards currently in effect for bottled water; and (4) require that any bottled water representing itself as derived from an underground source or containing naturally impregnated mineral solids include certain statements on its label. IBWA respectfully urges that this petition be approved in its entirety, but in the event that it is not, IBWA urges that its component parts be considered as severable and treated separately.

Action Requested

IBWA respectfully petitions the Commissioner to amend 21 CFR Parts 102 and 103 as follows:

1. Amend Part 102 to include new § 102.60 to read as follows:

"§ 102.60 Bottled Water

"(a) Common or Usual Name. The common or usual name of bottled drinking water products shall be:

"(1) A descriptive name for the product meeting the requirements of § 102.5(a); and

"(2) When the product (i) is naturally impregnated with at least 500 ppm of total dissolved mineral solids and (ii) is obtained from a spring or other underground water bearing stratum, the name shall be 'bottled mineral water';

"(3) When the product (i) is naturally impregnated with more than 250 ppm, but less than 500 ppm of total dissolved mineral solids and (ii) is obtained from a spring or other underground water bearing stratum, the name may be called 'bottled light mineral water'; and

"(4) When the product (i) is obtained from other than a spring or underground water bearing stratum, or contains dissolved mineral solids which are added to the product by other than natural means, and (ii) the label of such product represents, suggests or implies that the product is naturally impregnated with dissolved mineral solids (including use of

the term 'natural' on the product label), or the label of such product represents, suggests or implies that the product is obtained from a spring or underground water bearing stratum (including use of the terms "natural" or spring" on the product label), such label shall include (i) a statement indicating the general source of such bottled water, or (ii) a statement indicating that the product is not obtained from a spring or underground water bearing stratum.

"(b) Safety Criteria. For the purpose of this subsection, 'bottled water' is defined as water that is sealed in bottles or other containers and intended for human consumption. Bottled water does not include any food defined in § 165.175 of this chapter. Unless otherwise specified, bottled water does include bottled mineral water and bottled light mineral water.

"(1) Microbiological quality. Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of 'Standard Methods for the Examination of Water and Wastewater,' 14th Ed. (1975), American Public Health Association, which is incorporated by reference (copies are available from the Division of Food Technology, Bureau of Foods (HFF-210), 200 C St. SW., Washington, D.C. 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), meet the following standards of microbiological quality:

"(i) Multiple-tube fermentation method. Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

"(ii) Membrane filter method. Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

"(2) Chemical Quality.

"(i)(a) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (2)(i)(b) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

SUBSTANCE - Concentration in Milligrams Per Liter

	Bottled Water (Other than Bottled Mineral Water or Bottled Light Mineral Water)	Bottled Mineral Water	Bottled Light Mineral Water
Arsenic	0.05	0.5	0.05
Barium	1.0	10.0	1.0
Cadmium	0.01	0.1	0.01
Chloride	250.0		
Chromium	0.05	0.5	0.05
Copper	1.0		
Iron	0.3		
Lead	0.05	0.5	0.05
Manganese	0.05		
Mercury	0.02	0.2	0.02
Nitrate	10.0	100.0	10.0
Phenols	0.001		
Selenium	0.01	0.1	0.01
Silver	0.05	0.5	0.05

Sulfate.....250.0
Total dissolved
solids.....500.0
Zinc.....5.0

Organics (including bottled mineral water):
Endrin (1, 2, 3, 4, 10, 10-hexachloro-6, 7-epoxy-1, 4, 4a, 5, 6, 7, 8, 8a-Octahydro-1, 4-endo, endo-5, 8-dimenthano naphthalene).....0.0002
Lindane (1, 2, 3, 4, 5, 6-hexachlorocyclohexane, gamma isomer).....0.004
Methaoxychlor (1, 1, 1-trichloro-2, 2-bis[p-methoxy-phenyl] ethane).....0.1
Total Trihalomethanes 1/.....0.10
Toxaphene (C10H10CL8-technical chlorinated camphene, 67-69 percent chlorine).....0.005
2, 4-D (2, 4-dichlorophenoxyacetic acid....0.1
2, 4, 5-TP Silvex (2, 4, 5-trichlorophenoxypropionic acid).....0.01

"(b) Analyses conducted to determine compliance with paragraph (2)(i)(a) of this section shall be made in accordance with the methods described in the applicable sections of 'Standard Methods for the Examination of Water and Wastewater,' 14th Ed. (1975) or 'Methods for Chemical Analysis of Water and Wastes,' (1974), both of which are incorporated by reference. Analyses for organic substances shall be determined by appropriate methods described in 'Methods for Organochlorine Pesticides in Industrial Effluents' and 'Methods for Chlorinated Phenoxy Acid Herbicides in

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1/ "'Trihalomethane' (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

"'Total Trihalomethanes' (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane [chloroform], dibromochloromethane, bromodichloromethane and tribromomethane [bromoform]), rounded to two significant figures."

Industrial Effluents,' November 28, 1973, which are incorporated by reference, and 'Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method,' Method 501.1 and 'Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/ Liquid Extraction,' Method 501.2 in 40 CFR Part 141, Appendix C (45 FR 68672; November 29, 1979). The availability of these incorporations by reference are given in paragraph (1) of this section.

"(ii)(a) Bottled water packaged in the United States to which no flouride is added shall not contain flouride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter		
	Bottled Water (Other than Bottled Mineral Water or Bottled Light Mineral Water)	Bottled Mineral Water	Bottled Light Mineral Water
53.7 and below.....	2.4	24.0	2.4
53.8-58.3.....	2.2	22.0	2.2
58.4-63.8.....	2.0	20.0	2.0
63.9-70.6.....	1.8	18.0	1.8
70.7-79.2.....	1.6	16.0	1.6
79.3-90.5.....	1.4	14.0	1.4

"(b) Imported bottled water (other than imported bottled mineral water) and imported bottled light mineral water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter. Imported bottled mineral water to which no fluoride is added shall not contain fluoride in excess of 14.0 milligrams per liter.

"(c) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter		
	Bottled Water (Other than Bottled Mineral Water or Bottled Light Mineral Water)	Bottled Mineral Water	Bottled Light Mineral Water
53.7 and below.....	1.7	17.0	1.7
53.8-58.3.....	1.5	15.0	1.5
58.4-63.8.....	1.3	13.0	1.3
63.9-70.6.....	1.2	12.0	1.2
70.7-79.2.....	1.0	10.0	1.0
79.3-90.5.....	0.8	8.0	0.8

"(d) Imported bottled water (other than imported bottled mineral water) and imported bottled light mineral water to which fluoride is added shall not contain fluoride

in excess of 0.8 milligrams per liter. Imported bottled mineral water to which fluoride is added shall not contain fluoride in excess of 8.0 milligrams per liter.

"(3) Radiological quality.

"(i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (3)(ii) of this section, meet standards of radiological quality as follows:

"(a) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

"(b) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

"(c) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

"(ii) Analyses conducted to determine compliance with paragraph (3)(i) of this section shall be made in accordance with the methods described in the applicable sections

of 'Standards Methods for the Examination of Water and Wastewater,' 14th Ed. (1975), and 'Interim Radiochemical Methodology for Drinking Water,' Environmental Monitoring and Support Laboratory, EPA-600/4-75-008 (Revised), March 1976, U.S. Environmental Protection Agency, both of which are incorporated by reference. The availability of these incorporations by reference is given in paragraph (1) of this section.

"(4) Adulteration. Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the act is deemed to be adulterated, regardless of whether or not the bottled water meets the safety criteria established by subsection (b) of this section.

2. Amend Part 103 by deleting § 103.35.

Statement of Grounds

The Food and Drug Administration has for several years recognized the need to ensure the quality and safety of bottled water, which has become an increasingly common and accepted alternative to publicly supplied drinking water and traditional consumer beverages. In 1975, FDA first adopted (with technical assistance from the American Bottled Water Association, the predecessor to IBWA) regulations establishing Standards of Quality and Good Manufacturing Practices ("GMPs") for bottled water. FDA specifically exempted bottled mineral water from the Standards of Quality, not because mineral water is inherently safer than other kinds of bottled

water, but rather because FDA recognized that not all specifications appropriate to the regulation of bottled water are necessarily appropriate to the regulation of mineral water. Indeed, as the FDA stated in the preamble to the bottled water regulations published in 1979: "Mineral water is excluded in the quality standard definition because it is inherently different from other bottled water products and cannot be regulated by the specifications established for the quality of other bottled water products." 44 Fed. Reg. 12171 (March 6, 1979) (emphasis added).

Emphatically, FDA has never found that there is no need to regulate bottled mineral water from a safety or quality point of view. Because "natural" or unprocessed mineral water is not treated with chemicals, bottlers of natural mineral water are required to take substantial protective measures to ensure the quality of their product. These measures range from protecting the water source from biological and chemical contamination to controlling the sanitary conditions for bottling operations and distribution. While IBWA believes that bottlers of natural mineral water do in fact produce products of high quality and safety as a result of the protective measures they undertake voluntarily at great expense, the lack of federal standards undermines public confidence that all bottled mineral water meets minimum standards of safety.

The failure of FDA to establish safety standards for bottled mineral water has also resulted in a regulatory vacuum which has

been partially filled by haphazard and conflicting state regulation. 2/ Conflicting state regulations in turn create unnecessary and costly burdens on bottled mineral water companies whose products are shipped in interstate commerce.

Moreover, the failure to regulate bottled mineral water has resulted in substantial confusion in the public mind regarding the extent of federal regulation over the rest of the bottled water industry. While "mineral water" is exempted from the quality standards for bottled water, it is nowhere defined in FDA regulations. 3/ Thus the breadth of FDA regulation of bottled water, as well as the scope of the federal exemption for mineral water are highly ambiguous. Without a working definition of mineral water, even FDA's current regulatory scheme cannot be even-handedly administered. The result is frequent consumer misunderstanding that all bottled water is unregulated and growing conflict among state and local jurisdictions that flounder without guidance to fill the void left by FDA.

2/ California has established and Michigan has proposed differing regulations and definitions for bottled mineral water. It is IBWA's understanding that the States of New York, New Jersey, Maine and Pennsylvania are developing regulations for bottled mineral water which are expected to be different from those already adopted by California and proposed by Michigan.

3/ Current FDA regulations define "bottled water" as:

> Water that is sealed in bottles or other containers and intended for human consumption. Bottled water does not include mineral water or any food defined in § 165.175 of this chapter.

21 CFR § 103.35(a).

Finally, consumer confusion created by the lack of federal regulation of bottled mineral water extends to the difference between "natural" or unprocessed mineral waters, which are derived from underground sources, and "processed" mineral waters or surface waters impregnated with dissolved mineral solids. Because of growing consumer demand for bottled waters from natural sources, there is a great need to ensure that bottled water companies, whose sources of water are municipal supplies or surface waters such as rivers, lakes or ponds, do not engage in marketing practices that may lead consumers to believe that the water is from a protected underground source. Label terms such as "spring fresh" or "natural taste" or other use of the terms "spring" or "natural," if not appropriately qualified, may lead consumers to believe that such waters are derived from a protected underground source when in fact they may be derived from surface waters, processed by distillation, reverse osmosis, ion exchange or other treatment methods, and later impregnated with dissolved mineral solids.

IBWA believes that its proposed amendments address, in a practical and useful way, the serious problems created by the omissions in the current regulatory framework governing bottled water. Importantly, IBWA's proposals do not create undue administrative burdens for FDA or economic hardships for bottled water producers.

FDA has acknowledged the importance of defining "mineral water." FDA has failed to do so, however, because it claims it lacks sufficient data to set a standard of identity based on the concentration of dissolved mineral solids. Accordingly, IBWA proposes that

rather than subject bottled mineral water to a scientifically-based standard of identity, it be defined by its "common or usual name." IBWA's proposed definition incorporates the two elements which are commonly recognized by industry as necessary to any definition of bottled mineral water: (1) all mineral water is derived from an underground source, such as a spring or other underground water bearing stratum, and (2) all mineral water contains naturally impregnated mineral solids. While there may indeed be insufficient data at present to develop a scientifically or nutritionally-based standard of identity for bottled mineral water based on the level of dissolved mineral solids, the IBWA proposed "common or usual name" is based on an industry consensus that virtually every bottled mineral water product on the U.S. market today falls into one of two categories: "regular" bottled mineral water, which is marketed and sold on the basis of its distinctive taste in addition to its mineral content, and "light" bottled mineral water, which has a lower mineral content but which may be generally marketed and sold as a substitute for regular drinking water. In particular, the IBWA proposed "common or usual name" for bottled mineral water is based on an industry consensus that virtually every bottled mineral water product in the former category contains at least 500 ppm of total dissolved mineral solids, and that virtually every product in the latter category contains more than 250 ppm, but less than 500 ppm, of total dissolved mineral solids. Thus the IBWA proposed definition would

allow FDA to fulfill its regulatory mandate of ensuring the public health while avoiding the administrative difficulties inherent in developing a standard of identity for bottled mineral water based on nutritional or scientific distinctions.

Secondly, FDA has acknowledged the importance of ensuring that any food, including bottled mineral water, be safe and free of adulteration. While there may be disagreement among experts as to whether certain specifications currently applicable to bottled water generally should be extended to mineral water, there should be no disagreement as to the appropriateness of the health-related criteria proposed by IBWA regarding substances which are not among the normal dissolved mineral solid constituents of mineral water and which are based on EPA primary drinking water standards. While the current bottled water quality standards (and primary drinking water standards) are based on an average daily consumption of 2.2 liters, the proposed safety criteria for bottled mineral water are based on an average daily consumption level one-tenth that of ordinary bottled water or drinking water. On the other hand, since bottled light mineral water may be generally marketed and sold as a substitute for regular drinking water, the proposed safety criteria for this category are based on an average daily consumption of 2.2 liters.

Finally, FDA has acknowledged that representations regarding the source of bottled waters, including those involving use of terms such as "natural," should not be misleading to the consumer. However, FDA has indicated it has not issued regulations regarding

such representations because it has not established a general definition of the term "natural." IBWA's proposed regulation avoids the problems that would be involved in any comprehensive regulation governing bottler representations as to the source or "natural" qualities of their products. It does not attempt to define the term "natural." Rather it would merely require that any bottled water product, whose label erroneously represents, suggests or implies that the product is derived from a protected underground source or is naturally impregnated with dissolved mineral solids, include in its label a statement indicating the general source of such bottled water or a disclaimer that the product is obtained from a spring or other underground water bearing stratum.

The fact that mineral water is derived only from protected underground sources and is naturally impregnated with dissolved mineral solids is the fundamental characteristic of bottled mineral water and has a material bearing on the price and consumer acceptance of such products. General marketing research has established that consumers are looking for and are willing to pay more for bottled mineral water (1) which is derived from protected underground sources, as opposed to surface waters, and (2) which is naturally impregnated with dissolved mineral solids, as opposed to artificially processed waters. Further, compliance costs would be de minimis and would appear to be controversial only for those companies that attempt unfairly to market processed surface "mineral" waters as derived from underground sources.

In short, the IBWA proposal offers substantial protection to the consuming public, has the advantage of simplicity, and avoids undue administrative burdens to FDA and economic hardships to producers. For these reasons, IBWA respectfully urges the Commissioner to approve this petition.

Environmental Impact

The proposed amendments to FDA regulations are not considered a major agency action significantly affecting the quality of the human environment pursuant to 21 C.F.R. §25.1(a)(4) and thus do not require an environmental impact statement.

Certification

The undersigned certifies that, to the best of his knowledge and belief, 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,

Timothy L. Harker

PEABODY, LAMBERT & MEYERS
A Professional Corporation
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 457-1000

Counsel to the International
Bottled Water Association

IBWA NOTES

ROSTER UPDATE: Members are reminded to fill out and mail their 1983 IBWA Roster Update Form, which was sent with the dues renewal form. Members should check their listing as it appeared in the 1982 Roster and make any additions or corrections. In order to have a company listed in the new edition dues must be paid by February 28, 1983, and the update form returned.

1983 DUES INVESTMENT: 1983 dues are payable on January 1, 1983, and must be paid in part or in total by February 28, 1983. Any member having any questions about the dues schedule should contact IBWA.

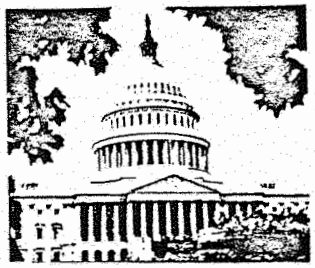
UNIFORM PATCHES: The brand new IBWA uniform patch was shown at the convention in October and orders are now being accepted. The attractive embroidered cloth patch has a blue background with white letters, "IBWA, International Bottled Water Association." Members are urged to purchase these and have drivers and employees wear them to identify IBWA membership to customers and the public. The cost of these patches is .75¢ each, and large quantity prices will be quoted.

BOTTLED WATER REPORTER: Articles and stories for the next six issues of the BOTTLE WATER REPORTER are being accepted. If you want your company featured or have news for the publication, please contact Lisa Manzolillo.

PUBLIC RELATIONS COMMITTEE: The 1983 IBWA Public Relations Committee will meet in Washington at the Hyatt Regency, Crystal City, on January 13, 1983. Austin Hess, chairman, invites all interested persons to attend or send ideas for projects to him.

THE BOTTLED WATER STORY: This recently announced publication has been altered slightly to make the piece a "self-mailer." Members can use this now either in their regular envelope or as a mailing piece addressed on the outside flap without an envelope. A second printing is already completed and orders are being accepted on additional copies.

The next meeting of the Board will be held February 2-4, 1983, at the Hyatt Maui, Hawaii. All members ar invited to attend or address any topics to be discussed to the IBWA office.



IBWA Regulatory Newsletter

Timothy L. Harker
Peabody, Lambert & Meyers
General Counsel,
International Bottled Water Association

IBWA Plans to Petition FDA for New Bottled Mineral Water Regulations

The International Bottled Water Association is preparing to petition the Food and Drug Administration to establish new rules which would regulate bottled mineral water. Currently FDA regulates the bottled water industry through the establishment of quality standards and Good Manufacturing Practices, but bottled mineral water was specifically exempted from the quality standard regulations.

IBWA's petition is intended to fill the "gap" in the FDA's regulatory scheme and to ensure that *all* bottled waters—including bottled mineral water—meet minimum standards of safety. In addition, the IBWA petition is intended to reduce potential consumer confusion over the source of any bottled water product that utilizes misleading labeling to imply that it is "natural" mineral water or "spring" water when, in fact, it is not. In short, the proposed IBWA petition would do the following:

(1) *Establish a "Common or Usual Name" for Bottled mineral water.* "Bottled mineral water" would be defined as a bottled water which is (i) naturally impregnated with at least 500 ppm of total dissolved mineral solids and (ii) derived from a spring or other underground water-bearing stratum. Any product meeting these requirements would have to be labeled as bottled mineral water.

(2) *Establish minimum safety criteria for bottled mineral water.* IBWA's proposed regulations would establish for the first time health-related safety standards for bottled mineral water. The proposed regulations would establish microbiological, radiological, and physical standards that are identical to those currently in effect for bottled water (found at 21 C.F.R. §103.35). The proposed regulations would also establish health-related chemical standards for bottled mineral water that are based on the health-related chemical standards now in effect for bottled water. However, since the chemical safety standards for bottled drinking water are based on an average daily consumption level that is thought to be approximately ten times the level of consumption of bottled mineral water, IBWA would propose maximum contaminant levels (MCLs) for health-related chemicals for bottled mineral water that are ten times the chemical standards for regular bottled drinking water.

(3) *Require bottled water labels to state the source of the water if the label claims or implies that the product is a "natural" mineral water or a "spring" water.* IBWA's proposed regulations would also address the potential problem of label misrepresentation that a bottled water is "natural" mineral water or "spring" water when, in fact, it is processed drinking water or natural water artificially impregnated with dissolved mineral solids. The proposed IBWA petition, if adopted by FDA, would require that when a bottled water represents that the product is naturally impregnated with minerals or is a natural water including use of the terms "natural" or "spring" on the product label, then the label shall include (i) a statement indicating the general souce (by geographic and descriptive statement, *i.e.* general location of the "spring" or other underground water-bearing stratum) of such bottled water, or (ii) a statement indicating that the product is not obtained from a spring or underground water-bearing stratum.

(4) *Maintain all quality standards for bottled drinking water currently in effect.* The IBWA petition would retain all quality standards currently in effect for bottled drinking water—both those that are health related and those that are not.

(5) *Establish separate safety criteria for bottled "light" mineral water.* The IBWA petition would also establish a common or usual name for a new category of drinking water called "light mineral water." Bottled light mineral water would be defined as a bottled water product which is (i) naturally impegnated with more than 250 ppm, but less than 500 ppm of dissolved mineral solids, and (ii) derived from a spring or other underground water-bearing stratum. Bottled light mineral water would have to meet the same safety criteria as regular bottled mineral water, except that the maximum contaminant levels for health-related chemicals would be the same as those now in effect for bottled drinking water (rather than ten times the maximum levels, as is proposed for regular bottled mineral water). Unlike bottled mineral water in excess of 500 ppm total dissolved solids, a product meeting the above requirements would be permitted, but not required, to be labeled as "light mineral water."

IBWA has developed this suggested approach only after exploratory meetings with officials of FDA, extensive evaluation of various options proposed by bottled water and bottled mineral water members and non-members, and thorough deliberations by the Government Relations Committee and the Board of Directors. *IBWA invites your comments on this suggested approach to the issues of mineral water definition and safety standards.* IBWA plans to submit a petition to the FDA within the next several weeks, or as soon as certain industry economic and mineral water consumption data necessary to support the petition are compiled. Under Federal law, the FDA must provide a response to the IBWA petition within 180 days of its filing. Please send your comments to IBWA, 1010 Vermont Ave., Washington, D.C. 20005.