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FDA-RTK

Study-2-2000-NRDC Comm... attached are NRDC's comments for docket #HFS-306. a hard copy was mailed today.

97N-0436

EMCH

**COMMENTS OF THE  
NATURAL RESOURCES DEFENSE COUNCIL**

**ON FDA's  
"DRAFT STUDY REPORT: FEASIBILITY OF  
APPROPRIATE METHODS OF INFORMING  
CUSTOMERS OF THE CONTENTS OF BOTTLED  
WATER"**

**Filed: April 24, 2000**

We are pleased that FDA concluded that “placing information on the label is an appropriate method of informing consumers about the contents of bottled water.” 65 Fed. Reg. at 8720. However, we are deeply concerned with the credence FDA gives to certain of industry’s specious arguments that bottle labels cannot be used to assure consumers’ right to know about bottled water quality. FDA asserts—echoing the arguments of the industry—that labels cannot feasibly convey information on the contaminants in the water because “there is a potential economic burden of frequent label changes if the particular information that is placed on the label requires frequent label changes as a result of ongoing monitoring of contaminants.” 65 Fed. Reg. at 8722. This problem can easily be avoided if FDA requires only annually updated label information on contaminants found in the bottled water; this would align with the annual updates required for public water systems’ Consumer Confidence Reports (CCRs). If information on hardness, pH, and mineral profile (information of little or no health consequence or consumer interest) can be included on the label, as it already is on many bottles, information of contaminants of potential health concern certainly can be included as well.

The bottled water industry’s other objection to label-based information—that it will lead to label clutter and confusion—also can be readily avoided. FDA can simply require that only certain key information be included on the label, with additional information available by other means (e.g. brochures at the point of sale, on the Internet, and via toll-free calls to bottlers).

NRDC strongly believes that at a minimum, it is feasible for labels to include, and FDA should require that labels include:

1. The level of any contaminant found in the water at a level in excess of a health goal (as defined below), plus the fluoride level and sodium level;
2. The health goal and allowable level for such contaminants;

3. A one-sentence, lay-person readable summary of the health effects associated with any contaminant found at a level in excess of a health goal;
4. A statement as to whether the bottler was, for the previous calendar year, in substantial compliance with state and FDA rules, and if not, what violations occurred;
5. A simplified statement of the EPA/CDC criteria for bottled water that should be used by immunocompromised persons to avoid *Cryptosporidium* contamination, and whether the water meets those criteria;
6. The specific source and treatment of the water;
7. An FDA toll free number for information (or EPA's Drinking Water Hotline);
8. The bottlers' street address, web and email addresses.
9. The date of bottling and an expiration date for the water.

From NRDC's extensive testing of over 1000 bottles of water, summarized in NRDC's 1999 Petition to FDA and the attached report Bottled Water: Pure Drink or Pure Hype?, it is a very rare water that has more than one or two contaminants found at levels in excess of health goals, so label clutter should not be a problem if our recommendations are followed. We reiterate a question we asked in our previous comments: if bottled water truly is so pure, as FDA and bottlers continually assert, why would a simple listing of contaminants found at levels in excess of health goals be lengthy and clutter a label?

## **II. Methods of Conveying Information to Consumers: The Label is Best, Though Additional Forms of Communication May Add to Effectiveness**

### **A. Consumers Want and Need Information on the Label**

As NRDC and several other environmental and consumer groups noted in our 1998 comments to FDA in response to FDA's November 12, 1997 Federal Register notice, 62 Fed. Reg. 60721 (comments that NRDC hereby incorporates by reference), labels are the best way to

reach consumers with information on bottled water contaminants, treatment, and source. It is through a review of labels that consumers get the most of their information about bottled water, and it is based upon information on the label that they make purchase decisions. Information that is only available through a web site or by making a phone call or writing to the bottler is unlikely to be useful to the vast majority of consumers.

FDA notes in its study that some “comments indicated that historically there has been little consumer interest in information on the contents of bottled water.” 65 Fed. Reg. at 8720. To the contrary, as FDA should know in the wake of NRDC’s 1999 report and other occurrences (such as the events following the Perrier bottled water contamination incident), there is staggering public interest in the quality of bottled water. For example, after NRDC released its petition to FDA and findings in early 1999, there were over 1,000 TV and radio stories on the issue, and NRDC received well over 1.3 million “hits” on its website in the days following the release of the report. This is hardly evidence of trivial public interest in the issue. Consumers Union, National Consumers League, and Consumer Federation of America, the three biggest consumer organizations in the nation representing millions of members, urged FDA to require disclosure of information on the contaminants in bottled water on the label in 1998 comments to FDA (see attached). Again, this is a strong indication of consumer demand for this type of information on the bottled water label.

**B. It is Entirely Feasible to Include Information on Bottled Water on the Label**

FDA suggests several reasons that it may be infeasible to include “all” CCR information on bottled water contents on the label. This is a straw man, however, because to NRDC’s

knowledge, no one was suggesting that labels include “all” information required to be included in the CCR on the label.

Each further argument that summary information on bottled water quality cannot feasibly be included on the label cannot withstand scrutiny. FDA admits that the “average cost of making a label change for firms in this industry [is] \$2,200 to \$17,900, depending on the complexity of the label change” and certain other factors—not exactly a staggering blow to the \$4,000,000,000.00 US bottled water industry. This is a cost that obviously can be absorbed by this immensely profitable bottled water industry; if the smallest tap water utilities can do it, so can for-profit bottlers.

Furthermore, FDA says it has “concerns about the economic feasibility of placing information on a label that has the potential to change on a frequent basis as a result of ongoing monitoring that is required” under FDA rules. *Id.* at 8720. However, this result is easily avoided by merely requiring bottlers to update their labels with information on contaminants found once a year—as is now required for CCRs from tap water utilities. FDA rules require that the vast majority of contaminants be tested only once a year. Information on microbial contaminants that are tested for weekly could simply be summarized with range and average information, as is now required in tap water utilities’ CCRs (which must summarize a year’s worth of monitoring that often occurs daily). Thus, by reporting ranges and averages of levels of contaminants found in the previous year in the water, bottlers can assure that the levels reported are accurate.

Of course, such an annual update requirement would not supersede the existing obligation of bottlers under FDA rules to include information on the label regarding any exceedence of an FDA bottled water allowable level. Nor would it supersede the requirement to disclose other hazards, to avoid misbranding the product under FDA’s current rules and FFDCa §403.

FDA also suggests that “economic hardship” may result and products may “bear a label that was no longer accurate, due to changing test results, which may cause the product to be misbranded....” *Id.* at 8720. Again, this argument cannot withstand a careful evaluation. If the FDA rules were simply to require an annual label update with the range and average levels of contaminants found in excess of health goals during the previous year, a label complying with such a requirement would not thereby be misbranded even if levels change with time. (We wonder whether FDA is suggesting that bottlers that now note on their labels their mineral and sodium levels, or that note their arsenic level as required by Vermont law—levels that vary with time—are misbranding their products?).

If subsequent tests showed that the water later violated an FDA allowable level or otherwise presented a significant health hazard, the bottler’s current obligation to disclose this fact on the label under FDA rules and FFDC § 403 should and would remain in effect. FDA could simply make it clear in its rules that these current obligations would in no way be superseded by the new additional labeling requirement.

Finally, echoing arguments of the bottled water industry, FDA argues that placing too much information on the label would result in “label clutter due to space requirements” and that therefore only certain unspecified information could be included on the label. In principle NRDC agrees that it probably would not be wise to attempt to reproduce every single requirement for a public water system CCR on a bottled water label due to a label clutter problem. However, this problem can be readily avoided if FDA distills the requirements down, so that only the most important summary information that consumers want and need are required to be on the label.

Moreover, it is quite feasible for bottlers to include neck hangers, fold outs, or other label devices (as Appollinaris and others already do—see NRDC et al. 1998 Comments and

attachments), to include this critical information if necessary. NRDC makes suggestions—tracking those made by NRDC, Consumers Union, Consumer Federation of America, and others in 1998, in the following section. Such limited summary information would readily fit on the vast majority of existing labels without any “clutter” problem.

C. Critical Information That Can Feasibly Be Included on Labels.

NRDC reiterates its position, noted in its joint 1998 comments with Consumers Union, Consumer Federation of America, the National Consumers League, and several other consumer and environmental groups, that certain critical information should and feasibly can be included on bottled water labels. To summarize those comments, the labels should include:

1. The level, in whole numbers, of any contaminant found in the water at a level in excess of a health goal (including EPA Maximum Contaminant Level Goals (MCLGs), or other health goals for drinking water defined in our 1998 comments), plus the fluoride level and sodium level;
2. The health goal and allowable level for such contaminants (we disagree with FDA’s suggestion, at 65 Fed. Reg. 8719, that the MCLGs are not relevant to bottled water—they are health-based goals for human consumption of drinking water, and are statutorily the basis of EPA’s tap water MCLs, which under the FFDCA §410 are the basis of FDA’s bottled water rules, and are therefore equally relevant to tap water and to bottled water consumers);
3. A one-sentence, lay-person readable summary of the health effects associated with any contaminant found at a level in excess of a health goal;
4. A statement as to whether the bottler was, for the previous calendar year, in substantial compliance with state and FDA rules, and if not, what violations occurred (based upon an annual sworn certification sent to the state and FDA, and not disagreed with in writing by either);
10. A simplified statement of the EPA/CDC criteria for bottled water that should be used by immunocompromised persons to avoid *Cryptosporidium* contamination, and whether the water meets those criteria;
5. The specific source (e.g. City of Akron Public Water System”) and treatment (e.g. reverse osmosis and ozone) of the water;

6. An FDA toll-free number for more information (or referral to EPA's Drinking Water Hotline, which could be equipped with information on bottled water with FDA assistance—we disagree with FDA's suggestion, 65 Fed. Reg. 8719, that the drinking water hotline is not relevant to bottled water consumers, since all of the same contaminants and many of the same standards are applicable to bottled and tap water);
7. Bottlers' street address, and web/email addresses.
8. The date of bottling and an expiration date for the water

Finally, we do not believe that it is necessary or wise to require pH, mineral profile, or hardness of the water, as most consumers likely have little interest in this information, and it will needlessly clutter the label with information with few or no health implications.

D. Other Methods of Informing Consumers May Be a Useful **Supplement** but not **Substitute** for Labels.

NRDC agrees with FDA that certain other methods of providing information to consumers other than through labels are feasible. For example, it is feasible to use pamphlets at the point of sale, to provide of addresses, phone numbers, and/or web/email addresses on labels, and to use brochures for hand delivery or mailing with invoices for bulk water purchasers. However, none of these methods are an adequate substitute for labels that include summary information, as suggested above. Only if consumers are well informed at the point of sale on the label will the information have any meaningful impact on consumer behavior.

**III. Concerns About FDA Delays and Lack of Resources for Bottled Water**

NRDC remains deeply concerned about the delays and lack of resources and commitment FDA has dedicated to carrying out the Safe Drinking Water Act Amendments of 1996's

mandates to evaluate how to inform consumers about what's in their bottled water. FDA's statement in the draft study that an evaluation of the legal authority and need for conveying information about the contents of bottled water to consumers is "beyond the scope" of this study is difficult to comprehend or justify. It renders FDA's study an empty and formalistic exercise that undercuts Congress' clear intent that FDA consider requiring water bottlers to provide information on bottled water to consumers. FDA has introduced a needless additional set of steps in front of itself in delaying any discussion of this critical issue.

The delays and lack of resources or effort dedicated to this process are manifest. The draft study was to be issued by February 6, 1998, and the final report was to be issued by February 6, 1999. SDWA 1996 Amendments §114(b). Thus, FDA is running over 2 years late.

We urge FDA to accompany the final Feasibility Study with proposed rules for requiring bottled water labels and consumer right to know information, as soon as possible and certainly no later than mid-2000, over a year and a half after the legal deadline for the final study and report.

### **III. Conclusion.**

NRDC appreciates FDA's finding that it is feasible to inform consumers of the quality of their bottled water. However, we urge that FDA reevaluate and reconsider whether a substantial amount of this information can be provided in summaries on bottled water labels.