

**Butler, Jennie C**

**From:** Lynn Thorp [lthorp@cleanwater.org]  
**Sent:** Monday, April 24, 2000 4:23 PM  
**To:** fdadockets@oc.fda.gov  
**Subject:** docket 97N-0436



fdacomment.doc

Please find attached and embedded our comments on docket 97N-0436, FDA Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water.

?

April 21, 2000

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

Comments on Food and Drug Administration Draft Study Report; Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

Docket No. 97N-0436

Please accept these as the comments of Clean Water Action on the draft study report on the feasibility of appropriate methods of informing customers of the contents of bottled water. Clean Water Action is a national citizens' organization working for clean, safe and affordable water, prevention of health-threatening pollution, creation of environmentally-safe jobs and businesses, and empowerment of people to make democracy work. Clean Water Action organizes strong grassroots groups, coalitions and campaigns to protect our environment, health, economic well-being and community quality of life.

It is essential that bottled water drinkers have access to information about the bottled water they purchase and consume. Important and valuable new information is now available about the tap water from public water systems due to the Consumer Confidence Report (CCR) provisions of the 1996 Amendments to the Safe Drinking Water Act (SDWA.) We appreciate this opportunity to comment on how FDA should implement SDWA's direction to determine how to provide comparable information about bottled water.

Information About the Contents of Bottled Water

The draft feasibility study does not make clear what information FDA thinks should be given about bottled water. The draft study lists six types of information that are required in CCR's and notes that of those, some are relevant only to public drinking water systems. Those judged not relevant to bottled water are the "definition and statement of MCLG's

and information on public drinking water systems operating under a variance and other information that is relevant only to public drinking systems regulated by EPA, such as EPA's drinking water hotline." From the aforementioned list of CCR requirements, this would leave only the source of the water and a statement that the presence of contaminants does not necessarily indicate that the drinking water poses a health risk. It is unclear whether FDA is suggesting that these would be the only points of information provided.

FDA states that discussion is limited to information "...within the context of the SDWA Amendments (i.e. analogous to information outlined by EPA for inclusion in a CCR)..." We disagree that two are the same thing and with FDA's decision to limit the discussion in this way. The intent of the CCR's as outlined in the SDWA Amendments is to give consumers relevant and valuable information about their drinking water. The intent is the same for providing information about bottled water, whether that information is required in CCR's from public water systems or not.

Therefore, bottled water labels should include the following information:

(1) The level, expressed in whole numbers, of any contaminant found in the water at a level in excess of a health goal, plus the fluoride level (because of the element's asserted public health benefits at low levels and, at high levels, its detrimental effects), sodium level (to assist those seeking to reduce their sodium intake for health reasons);

(2) The health goal and allowable level for those contaminants found in the water and noted in #1, in the same units;

(3) A statement as to whether the bottler is in substantial compliance with state and federal regulations (based upon an annual certification sent to the state and FDA and not disagreed with in writing by either), and if not, what violations occurred;

(4) 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 (taken from model language written by FDA and EPA);

(5) A simplified restatement of the EPA/CDC advice to immuno-compromised consumers about the types of bottled water treatment necessary to avoid *Cryptosporidium* contamination, and whether the bottled water meets those criteria.

(6) The specific source (e.g. "Houston public water system") and treatment (e.e. "reverse osmosis and ozonation") of the water;

(7) An FDA toll free number for consumers to obtain more information (or a referral to EPA's drinking water hotline;)

(8) The bottler's street address, phone number and web or email address (if any,) for further

information.

We disagree with the exclusion of information on health goals (MCLG's.) While we recognize that bottled water is not regulated under the same system as drinking water, we believe that for consistency this is still the best information for drinking water consumers to receive, whether they are getting that water from a public water system or from a bottler.

#### Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

We think the basic information listed above should be included on the label and that current labeling methods leave room for this addition with out undue "label clutter." Since CCR's are prepared and distributed annually, a label change would generally not be required any more frequently.

All bottled water labels should contain a phone number and address which consumers can contact for further information, but this should not be a substitute for providing the basic information listed above on the label.

We do not support the "combination" approach, which would limit the information provided on the label and reserve the rest to be available by phone or mail. This places a burden on the consumer and deprives them of potentially important health information.

We agree with FDA that for practical reasons a pamphlet at the point of purchase is not feasible.

Bills or invoices for bulk delivery should include the information contained on the retail label; a label on the bulk delivery bottles should also be standard.

While internet information is a good supplement to the label, like the phone and address it should be just that – a supplement – and not a substitute for provision of the necessary information on the label.

We request that you give serious attention to these comments in preparation for publication of the final report. Given that over half of the U.S. population drinks bottled water at least some of the time, it is essential that these consumers be given information commensurate to that which they now receive for drinking water from public water systems.

--  
Lynn Thorp; lthorp@cleanwater.org  
Clean Water Action  
202-895-0420 ext. 109; 202-895-0438 fax  
4455 Connecticut Ave. NW; Suite A300; Washington DC 20008-2328

April 21, 2000

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

**Comments on Food and Drug Administration Draft Study Report; Feasibility of  
Appropriate Methods of Informing Customers of the Contents of Bottled Water**

**Docket No. 97N-0436**

Please accept these as the comments of Clean Water Action on the draft study report on the feasibility of appropriate methods of informing customers of the contents of bottled water. Clean Water Action is a national citizens' organization working for clean, safe and affordable water, prevention of health-threatening pollution, creation of environmentally-safe jobs and businesses, and empowerment of people to make democracy work. Clean Water Action organizes strong grassroots groups, coalitions and campaigns to protect our environment, health, economic well-being and community quality of life.

It is essential that bottled water drinkers have access to information about the bottled water they purchase and consume. Important and valuable new information is now available about the tap water from public water systems due to the Consumer Confidence Report (CCR) provisions of the 1996 Amendments to the Safe Drinking Water Act (SDWA.) We appreciate this opportunity to comment on how FDA should implement SDWA's direction to determine how to provide comparable information about bottled water.

**Information About the Contents of Bottled Water**

The draft feasibility study does not make clear what information FDA thinks should be given about bottled water. The draft study lists six types of information that are required in CCR's and notes that of those, some are relevant only to public drinking water systems. Those judged not relevant to bottled water are the "definition and statement of MCLG's and information on public drinking water systems operating under a variance and other information that is relevant only to public drinking systems regulated by EPA, such as EPA's drinking water hotline." From the aforementioned list of CCR requirements, this would leave only the source of the water and a statement that the presence of contaminants does not necessarily indicate that the drinking water poses a health risk. It is unclear whether FDA is suggesting that these would be the only points of information provided.

FDA states that discussion is limited to information "...within the context of the SDWA Amendments (i.e. analogous to information outlined by EPA for inclusion in a CCR)..." We disagree that two are the same thing and with FDA's decision to limit the discussion in this way. The intent of the CCR's as outlined in the SDWA Amendments is to give consumers relevant and valuable information about their drinking water. The intent is the same for providing information about bottled water, whether that information is required in CCR's from public water systems or not.

Therefore, bottled water labels should include the following information:

- (1) The level, expressed in whole numbers, of any contaminant found in the water at a level in excess of a health goal<sup>1</sup>, plus the fluoride level (because of the element's asserted public health benefits at low levels and, at high levels, its detrimental effects), sodium level (to assist those seeking to reduce their sodium intake for health reasons);
- (2) The health goal and allowable level for those contaminants found in the water and noted in #1, in the same units;
- (3) A statement as to whether the bottler is in substantial compliance with state and federal regulations (based upon an annual certification sent to the state and FDA and not disagreed with in writing by either), and if not, what violations occurred;
- (4) 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 (taken from model language written by FDA and EPA);
- (5) A simplified restatement of the EPA/CDC advice to immuno-compromised consumers about the types of bottled water treatment necessary to avoid *Cryptosporidium* contamination, and whether the bottled water meets those criteria.
- (6) The specific source (e.g. "Houston public water system") and treatment (e.e. "reverse osmosis and ozonation") of the water;
- (7) An FDA toll free number for consumers to obtain more information (or a referral to EPA's drinking water hotline;)
- (8) The bottler's street address, phone number and web or email address (if any,) for further information.

---

<sup>1</sup> The Term "health goal" refers to an EPA Maximum Contaminant Level Goal, if any, or if there is no MCLG, the lowest EPA Health Advisory Level (HAL,) or if there is no MCLG or HAL, the lowest EPA human health-based water quality criteria for that contaminant.

We disagree with the exclusion of information on health goals (MCLG's.) While we recognize that bottled water is not regulated under the same system as drinking water, we believe that for consistency this is still the best information for drinking water consumers to receive, whether they are getting that water from a public water system or from a bottler.

#### Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water

We think the basic information listed above should be included on the label and that current labeling methods leave room for this addition with out undue "label clutter." Since CCR's are prepared and distributed annually, a label change would generally not be required any more frequently.

All bottled water labels should contain a phone number and address which consumers can contact for further information, but this should not be a substitute for providing the basic information listed above on the label.

We do not support the "combination" approach, which would limit the information provided on the label and reserve the rest to be available by phone or mail. This places a burden on the consumer and deprives them of potentially important health information.

We agree with FDA that for practical reasons a pamphlet at the point of purchase is not feasible.

Bills or invoices for bulk delivery should include the information contained on the retail label; a label on the bulk delivery bottles should also be standard.

While internet information is a good supplement to the label, like the phone and address it should be just that – a supplement – and not a substitute for provision of the necessary information on the label.

We request that you give serious attention to these comments in preparation for publication of the final report. Given that over half of the U.S. population drinks bottled water at least some of the time, it is essential that these consumers be given information commensurate to that which they now receive for drinking water from public water systems.