Plain Language **Action & Information Network**

"Plain Language for An Informed Nation"

Dockets Management Branch (HFA-305) 3/21/2003
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To the Dockets Management Branch:

Re: Docket No. 03N-0068, "Beverages: Bottled Water; Companion Document to Direct Final Rule," 68 FR 9955

I'm commenting on this proposed rule as the Chair of the Plain Language Action and Information Network (PLAIN), a group advocating the use of plain language in written communications. Our members are representatives of Federal agencies and private organizations who support clear writing in government documents. Plain language has a solid record of reducing misunderstanding, improving compliance, fostering public trust in government, and advancing other goals of Federal programs.

Executive Orders 12866 and 12988 and the Presidential Memorandum of July 1, 1998, require Federal agencies to use plain language in drafting regulations. This proposed rule does not meet the plain language requirements of the Executive Orders or the Presidential Memorandum. The rule as proposed suffers from these problems:

1. The rule uses the passive voice. Active voice is the superior choice for regulatory writing because it removes possible ambiguity by stating clearly who does what. Writing this rule in the passive voice makes it:

- Difficult to understand, since the passive voice is harder for readers to follow

- Ambiguous, since it creates doubt about who is responsible for doing what

Awkwardly written, since it requires more words that the active voice

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Because you wrote this rule in the passive voice, it was difficult for us to tell who you are addressing. In our enclosed rewrite we assumed that producers will conduct the required analyses. If this is incorrect, you simply need to substitute the correct word wherever we have written "producer."

2. The rule doesn't use tables to clarify provisions for the reader. Setting out material in tables shows the reader at a glance what your main ideas are and how the subordinate points relate to those main ideas. As our rewrite shows, your requirement that producers conduct analyses using specific methods for particular elements is a perfect use for a table. Tabulating this material will make it much easier for producers to find and use the correct methods. It also eliminates redundant citations and thus deletes 452 unnecessary words.

From the proposed rule as published, we could not be certain if, in paragraphs (A), (C), and (D), you require analysis using methods (1) and (2) or using methods (1) or (2). If we have surmised incorrectly, you need only substitute "or" for "and" in paragraphs (A), (C), and (D).

3. The rule uses the imprecise word "shall." Shall is an imprecise word that creates ambiguity and uncertainty. In his *Dictionary of Modern Legal Usage*, Brian Garner points out that "shall" has as many as eight different meanings. He also says that, "courts in virtually every English-speaking jurisdiction have held – by necessity – that *shall* means *may* in some contexts, and vice versa." Because this proposed rule relates to the nation's health, accuracy is extremely important. For that reason, in our rewrite we have changed the word "shall" to the more precise and unambiguous "must."

I am enclosing a copy of our plain language rewrite of this rule. Please note that, because this is such a small revision, we have done a modest rewrite that requires you to make only minimal changes. In a more extensive rewrite, we could make many more changes to further improve readability. We can work with you to change this rewrite as necessary or to test it with members of the public. We can also provide plain language courses and ongoing drafting and reviewing assistance to your agency.

I would be happy to discuss this rewrite with you. Please feel free to contact me by e-mail or telephone.

Sincerely,

Annetta Cheek, Ph.D.
Chair

Enclosure

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PART 165--BEVERAGES

1. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343-l, 348, 349, 371, 379e.

2. FDA amends section 165.110 by adding paragraph (b)(5)(i)(D) and by revising paragraph (b)(5)(ii) to read as follows:

Sec. 165.110 Bottled water.

* * * * *

(b)* * *

(5) * * *

(i) * * *

(D) The bottled water may not contain more than 30 micrograms of uranium per liter of water.

(ii) Producers must conduct analyses to determine compliance with the requirements of paragraph (b)(5)(i) of this section. To conduct these analyses, producers must use the methods in "Standard Methods for the Examination of Water and Wastewater," 20th Ed. ("Standard Methods"), which is incorporated by reference under 5 U.S.C. 552(a) and 1 CFR part 51. Anyone can buy copies of "Standard Methods" from the American Public Health Association, 1015 15th St. NW., Washington, DC 20005. Anyone can examine "Standard Methods" at the Office of the Federal Register, 800 North Capital St. NW., suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD. The following table shows which method from "Standard Methods" analysts must use in specific cases:

To measure...	**use the following methods...**
(A) Combined radium-226/-228	*(1)* Method 7500-Ra B--"Precipitation Method"; and *(2)* Method 7500-Ra D--"Sequential Precipitation Method."
(B) Gross alpha particle radioactivity	Method 7110 C--"Coprecipitation Method for Gross Alpha Radioactivity in Drinking Water."
(C) Beta particle and photon radioactivity	*(1)* Method 7500-Sr B--"Precipitation Method"; *(2)* Method 7500-\3\H B--"Liquid Scintillation Spectrometric Method"; and *(3)* Method 7120 B--"Gamma Spectroscopic Method."
(D) Uranium	*(1)* Method 7500-U B--"Radiochemical Method"; and *(2)* Method 7500-U C--"Isotopic Method."