

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 98N-0294]

**Bottled Water: Monitoring Requirements****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the monitoring requirements under the national primary drinking water regulations (NPDWR's) found in 40 CFR part 141 for antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8-TCDD (dioxin), will be considered to be the standard of quality regulations applicable to these chemical contaminants in bottled water.

**DATES:** Effective February 2, 1999.

**FOR FURTHER INFORMATION CONTACT:** Henry Kim, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-0631.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 26, 1996 (61 FR 13258), FDA published a final rule (the March 1996 final rule) in which it amended the bottled water quality standard in 21 CFR part 165 by establishing allowable levels for 24 chemical contaminants in bottled water. In that final rule, FDA stayed the effective date for the allowable levels for nine of the chemical contaminants, specifically, antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8-TCDD (dioxin). As a result, the current good manufacturing practice (CGMP)

regulations under part 129 (21 CFR part 129) for bottled water were not in effect for these nine contaminants during the period of the stay.

Subsequent to the March 1996 final rule, on August 6, 1996, the Safe Drinking Water Act (SDWA) Amendments were enacted. Under the SDWA Amendments (section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349(b)(1)), for contaminants covered by a standard of quality regulation promulgated by FDA before the enactment of the SDWA Amendments for which an effective date had not been established (i.e., standard of quality regulations for the nine chemical contaminants: antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin), FDA is required to promulgate monitoring requirements for such contaminants not later than 2 years after the date of enactment of the SDWA Amendments, i.e., by August 6, 1998. If FDA does not meet this statutory time period, the NPDWR's for the nine chemical contaminants are considered to be the standard of quality regulation, and therefore, the monitoring requirements under the NPDWR are applicable to bottled water, and are to take effect no later than February 2, 1999.

Under this statutory mandate, FDA published a direct final rule on May 11, 1998 (63 FR 25764), to lift the stay of the effective date for the allowable levels in the bottled water quality standard for nine chemical contaminants. An effect of the direct final rule would have been to promulgate FDA's existing monitoring requirements for bottled water as the monitoring requirements for these nine contaminants in bottled water. By lifting the stay of the effective

date, bottled water manufacturers would have been required to monitor source waters and finished bottled water products at least once a year for these nine chemical contaminants under the CGMP regulations for bottled water in part 129. FDA also published a companion proposed rule in the same issue of the **Federal Register**.

Because FDA received significant adverse comment about monitoring requirements for these nine contaminants, FDA is unable to promulgate monitoring requirements for the nine contaminants by August 6, 1998. Therefore, the monitoring requirements under the NPDWR's for these nine contaminants shall be considered, under section 410(b)(4)(A) of the act, to be the standard of quality regulation for bottled water. FDA is giving notice, as required by section 410(b)(4)(B) of the act, that the monitoring requirements for these nine contaminants in the NPDWR's in 40 CFR part 141 are the monitoring requirements for these nine contaminants in bottled water, effective February 2, 1999. FDA intends to provide guidance concerning how it will apply these requirements to bottled water in the near future. Furthermore, FDA plans to publish a withdrawal of the companion proposed rule (63 FR 25789, May 11, 1998) that published on the same day as the direct final rule. The direct final rule is discussed elsewhere in this issue of the **Federal Register**.

Dated: August 4, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy  
Commissioner.*

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