

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 165**

[Docket No. 98N-0294]

**Beverages: Bottled Water****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Direct final rule; confirmation.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the provisions in the direct final rule that published in the **Federal Register** of May 11, 1998, to lift the stay of the effective date for the allowable levels in the bottled water quality standard for nine chemical contaminants, i.e., antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8-TCDD (dioxin), which were published on March 26, 1996.

**DATES:** The effective date for the rule published at 63 FR 25764 (May 11, 1998) and corrected at 63 FR 30620 (June 5, 1998) is confirmed as 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:** FDA published a direct final rule on May 11, 1998 (63 FR 25764), that was intended to lift the stay of the effective date for the allowable levels in the bottled water quality standard (§ 165.110 (21 CFR 165.110)) for nine chemical contaminants, i.e., antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and dioxin, that the agency established in a final rule that published on March 26, 1996 (61 FR 13258). By lifting the stay of the effective date, each lot of bottled water would be required to comply with the allowable levels for these nine chemical contaminants and bottled water manufacturers would be required to monitor source waters and finished bottled water products at least once a year for these nine chemical contaminants under the current good manufacturing practice (CGMP) regulations for bottled water in part 129 (21 CFR part 129). In response to the direct final rule, FDA received no significant adverse comment about lifting the stay of the effective date for the allowable levels for the nine chemical contaminants in the quality standard for bottled water (§ 165.110). However, FDA received a significant adverse comment about the monitoring

requirements in part 129 that would apply to these nine chemical contaminants as a result of the lifting of the stay. Because of the significant adverse comment received, FDA is unable to promulgate monitoring requirements within the statutory time period, i.e., by August 6, 1998, set forth in section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349(b)(1)). Therefore, each lot of bottled water will be required to comply with the allowable levels for these nine chemical contaminants, however, the monitoring requirements in part 129 do not apply to the nine chemical contaminants in bottled water and instead, under section 410(b)(4)(B) of the act, FDA is addressing monitoring requirements for the nine chemical contaminants in bottled water in a companion notice published elsewhere in this issue of the **Federal Register**.

FDA is confirming the lifting of the stay of the effective date for the allowable levels in § 165.110 for the nine chemical contaminants, effective February 2, 1999.

Dated: August 4, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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