

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 129 and 165

[Docket No. 01N-0126]

DMS

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Beverages: Bottled Water; Technical Amendment; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; technical amendment; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of January 1, 2002, for the direct final rule that appeared in the **Federal Register** of March 28, 2001 (66 FR 16858). The direct final rule amends the bottled water quality standard regulations (part 165 (21 CFR part 165)) by establishing allowable levels for three residual disinfectants (chloramine, chlorine, and chlorine dioxide) and three types of disinfection byproducts (DBPs) (bromate, chlorite, and haloacetic acids (HAA5)) and revised the existing allowable level in part 165 for the DBP total trihalomethanes (TTHM). The direct final rule also revised, for the three residual disinfectants and four types of DBPs only, the monitoring requirement for source water found in the current good manufacturing practice (CGMP) regulations for bottled water in part 129 (21 CFR part 129). FDA is also making a technical amendment to part 165 to correct an editorial error introduced in the direct final rule of March 28, 2001 (66 FR 16858 at 16866). This document confirms the effective date of the direct final rule.

DATES: The effective date for the regulation confirmed: January 1, 2002. The technical amendment to part 165 is also effective January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-358-3568.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 28, 2001 (66 FR 16858), FDA gave interested persons until June 11, 2001, to comment on the direct final rule. FDA stated that the effective date of the direct final rule would be January 1, 2002, and, if the agency received no significant adverse comment, it would publish a notice of confirmation of the effective date no later than July 5, 2001. FDA received no significant adverse comments within the comment period. Therefore, FDA is confirming that the effective date of the regulation is January 1, 2002.

As noted in the direct final rule, FDA is publishing this confirmation notice 180 days before the effective date to permit affected firms adequate time to take appropriate steps to bring their product into compliance with the standard imposed by the new rule. However, FDA recognizes that some bottled water products may be in the marketplace and remain there for 2 or more years. Thus, there may be some products already in interstate commerce on the effective date that have not been tested under the new part 129 requirements for disinfectants and disinfection by-products and that do not meet the revised standard of quality.

Under 403(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 (h)(1)), such products are considered to be misbranded if they do not meet the revised quality standard for the three residual disinfectants and the four types of DBPs unless they bear a statement of substandard quality. However, FDA believes that it would be appropriate to exercise its enforcement discretion as to those bottled water products that: (1) Are already in interstate commerce before January 1, 2002; (2) do not meet the revised quality standard for the three residual disinfectants and the four types of DBPs; and (3) do not bear a statement of substandard quality—provided that such products are not adulterated. Therefore, the agency does not plan to take enforcement action against such bottled water products, provided that such products are safe.

FDA is making a technical amendment to part 165 to correct an editorial error introduced in the direct final rule of March 28, 2001 (66 FR 16858 at 16866). In §165.110(b)(1)(ii), the agency is correcting the phrase “three significant figures” to read “two significant figures.” The error also appears in 21 CFR part 165.100 (21 CFR revised as of April 1, 2001), on page 535,

in the first column, under "Effective Date Note." Publication of this document constitutes final action of this change under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, notice is given that no objections or requests for a hearing were filed in response to the March 28, 2001, direct final rule. Accordingly, the amendments issued thereby, including the technical amendment below, are effective January 1, 2002.

List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 165 is amended as follows:

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, 343-1, 348, 349, 371, 379e.

2. Section 165.110 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 165.110 Bottled water.

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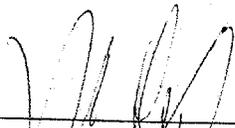
(b) * * *

(1) * * *

(ii) *Total trihalomethanes* (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane, and tribromomethane), rounded to two significant figures.

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Dated: 6/29/01
June 29, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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COPY OF THE ORIGINAL**



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