DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 95N–0203]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to exempt mineral water from the allowable level for aluminum in FDA's quality standard for bottled water. The agency is also proposing to update the testing methods referenced in the quality standard for bottled water. Elsewhere in this issue of the Federal Register, the agency is publishing a final rule to establish a standard of identity for bottled water. This proposal addresses two related issues that fell outside the scope of that rulemaking. FDA tentatively concludes that the proposed actions will promote honesty and fair dealing in the interest of consumers.

DATES: Written comments by January 29, 1996. The agency intends to make any final rule based upon this proposal effective 60 days following the date of publication of the final rule in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681.

SUPPLEMENTARY INFORMATION:

I. Background

On January 5, 1993 (58 FR 393), FDA published a proposal in the Federal Register to establish a standard of identity in § 165.110(a) (21 CFR 165.110(a)) for bottled water. At the same time, the agency proposed to recodify the standard of quality for bottled water, which is currently found in § 103.35 (21 CFR 103.35), to § 165.110(b), (c), and (d). In addition, FDA proposed to define ''artesian water,'' ''ground water,'' ''mineral water,'' ''purified water,'' ''spring water,'' and ''well water.''

Elsewhere in this issue of the Federal Register, FDA is issuing a final rule that implements those proposed actions. However, two related issues, which fell outside the scope of that rulemaking, are discussed in this document along with the comments that the agency received on those matters.

A. Exemption for Aluminum

In the January 5, 1993, proposal (58 FR 393 at 396), FDA proposed to include mineral water in the standard for bottled water and, thus, to subject mineral water to the requirements of the quality standard for bottled water. Some allowable levels in the quality standard are based on the Environmental Protection Agency (EPA) secondary maximum contaminant levels (SMCL's) that are established for aesthetic reasons and not for consumer safety. Mineral water with a high mineral content may not meet these allowable levels. Therefore, the agency tentatively concluded that certain aesthetically based allowable levels should not apply to mineral waters (58 FR 393 at 400). Elsewhere in this issue of the Federal Register, FDA is exempting mineral water from the allowable levels for color, odor, total dissolved solids, chloride, iron, manganese, sulfate, and zinc.

FDA stated in the January 5, 1993, proposal that if it established an allowable level for aluminum, it would propose to exempt mineral water from that standard because the standard is intended to control aesthetic properties of the water, and not its effect on the body (58 FR 393 at 401). EPA established an SMCL of 0.2 milligram per liter (mg/L) for aluminum because of increased turbidity of the water and to prevent post-treatment precipitation in public water distribution systems ((56 FR 3526, January 30, 1991). On December 1, 1994 (59 FR 61529), FDA established an allowable level of 0.2 mg/L for aluminum in bottled water in § 103.35(d)(3)(iv) (recodified as § 165.110(b)(4)(iii)(D) elsewhere in this issue of the Federal Register).

In response to the January 5, 1993, proposal, FDA received one comment that expressed concern about the proposed allowable level for aluminum in bottled water and with exempting aluminum in mineral water from the quality standard, because there are some data that suggest that there may be a link between aluminum and Alzheimer's Disease and other adverse health effects. It recommended that FDA maintain an allowable level of 0.2 mg/L for aluminum in all bottled water.

The agency disagrees with the comment. EPA established a SMCL for aluminum to control aesthetic properties of the water (turbidity) and not its effect on the body. Aluminum has been found to be neurotoxic when injected into the brains of animals and in renal patients dosed inappropriately with aluminum salts. However, the current evidence suggests that aluminum neither causes Alzheimer's disease nor contributes to the expression of Alzheimer's disease (Ref. 1).

Therefore, the agency tentatively concludes that it is appropriate to exempt mineral water from the allowable level of 0.2 mg/L for aluminum in § 165.110(b)(4)(iii)(D) because it is an aesthetically-based (turbidity) allowable level. Accordingly, the agency is proposing to add a footnote to the list of allowable levels in § 165.110(b)(4)(iii)(D) to provide that when water is labeled as ''mineral water,'' it will be exempt from the allowable level for aluminum. FDA is not proposing to include bottled waters that are not conspicuously identified with the term ''mineral'' in this exemption because consumers will not generally expect to encounter aesthetic effects typical of high mineral content waters in these bottled waters products. In addition, the agency is not proposing to exempt mineral water from the allowable level for turbidity because high turbidity may interfere with disinfection and microbiological determinations. This exemption parallels the exemptions in § 165.110(b)(3) and (b)(4)(i)(A) that FDA is establishing in a final rule published elsewhere in this issue of the Federal Register that exempts mineral water from certain other aesthetically based allowable levels.

B. Updating References

In the proposal to establish a standard of identity for bottled water (58 FR 393, January 5, 1993), the agency proposed to update the methods referenced in § 165.110(b)(2) and (b)(3) for testing water for the listed contaminants to the ''Standard Methods for the Examination of Water and Wastewater,'' 17th edition (1989). Several comments received in response to that proposal stated that § 165.110(b)(2) and (b)(3) should be updated and should reference ''Standard Methods for the Examination of Water and Wastewater,'' 18th edition (1992). However, because the agency failed to state in the proposal that it intended to update the references to the latest edition, the comments' requested change did not fall within the scope of that rulemaking, and a separate rulemaking was necessary to effect that change.

Title 1, part 51 of the Code of Federal Regulations (1 CFR part 51) requires the filing and updating of material that has

been incorporated by reference in the Code of Federal Regulations. The purpose of the requirement is to ensure the public availability and accuracy of material that has been incorporated from other sources.

In the Federal Register of October 6, 1993 (58 FR 52042), FDA proposed to update the reference in § 165.110(b)(2) to the 18th edition. The agency expects to adopt that modification in a final rule that will be published in the near future. However, to ensure the accuracy of methods for testing bottled water, that are referenced in § 165.110(b)(3), FDA is proposing to update them to reference ''Standard Methods for the Examination of Water and Wastewater,'' 18th edition (1992). If subsequent editions of the methods referenced are published before the completion of this rulemaking, the agency intends to update the references in § 165.110(b)(2) and (b)(3) to reflect the most recent edition.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impact of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues. The Regulatory Flexibility Act requires agencies to minimize the economic impact of their regulations on small entities. FDA finds that this proposed rule is neither an economically significant nor significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small entities.

Updating the references is not expected to significantly affect the content of those references or the cost of complying with regulations citing those references. FDA requests comments on any costs generated by updating the references as proposed.

Exempting mineral water from the allowable level for aluminum in bottled water does not represent a change from the current situation. There is currently no limitation on the amount of aluminum in mineral water. Similarly, there is no limitation on the amount of aluminum in mineral water under this proposal (other than a level that is injurious to health). The current situation is the baseline in comparison with which costs and benefits of proposed actions are measured. Therefore, there are neither costs nor benefits associated with exempting mineral water from the allowable level for aluminum in bottled water.

IV. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Humphreys, S., Contaminants, Standards, and Monitoring Branch (HFS–308F), Center for Food Safety and Applied Nutrition, Food and Drug Administration, memo to Shellee Davis, May 26, 1995.

V. Comments

Interested persons may, on or before January 29, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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, it is proposed that 21 CFR part 165 be amended as follows:

PART 165—BEVERAGES

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

Authority: Secs. 201, 401, 403, 403A, 409, 410, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 343A, 348, 349, 371, 379e).

2. Section 165.110 is amended by revising the introductory text of paragraph (b)(3) and by revising paragraph (b)(4)(iii)(D) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(3) Physical quality. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of ''Standard Methods for the Examination of Water and Wastewater,'' 18th ed. (1992), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (b)(2) of this section), meet the following standards of physical quality:

* * * * *

(4) * * *

(iii) * * *

(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2[1]
Silver	0.1

[1] Mineral water is exempt from the allowable level. The exemption is an aesthetically based allowable level and does not relate to a health concern.

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Dated: November 3, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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