

of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

### VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive Order requires agencies to “construe \* \* \* a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 403A of the act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a)(1) provides that “no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g) \* \* \*” FDA has interpreted this provision to apply to standards of quality (21 CFR 100.1(c)(4)). Although this rule has preemptive effect in that it would preclude States from issuing requirements for uranium levels in bottled water that are not identical to the allowable level for uranium as set forth in this rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

Section 4(c) of the Executive Order further requires that “any regulatory preemption of State law shall be restricted to the minimum level necessary” to achieve the regulatory objective. Under section 410 of the act, not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-1), FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled water. Further, section 410(b)(3) of the act requires a quality standard for a contaminant in bottled water to be no less stringent than EPA’s MCL and no less protective of the public health than EPA’s treatment techniques required for the same contaminant. On

December 7, 2000, EPA issued an NPDWR containing an MCL for uranium (65 FR 76708). FDA has determined that the MCL for uranium that EPA established for public drinking water is appropriate as a standard of quality for bottled water, and is issuing this regulation consistent with section 410 of the act.

Further, section 4(e) of the Executive Order provides that “when an agency proposed to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” Given the statutory framework of section 410 of the act for bottled water, EPA’s issuance of an MCL for uranium in public drinking water provided notice of possible FDA action for a standard of quality for uranium in bottled water. FDA did not receive any correspondence from State and local officials regarding a uranium standard for bottled water subsequent to EPA’s NPDWR on the MCL for uranium. Moreover, FDA is not aware of any States that have requirements for uranium in bottled water that would be affected by FDA’s decision to establish a bottled water quality standard for uranium that is consistent with EPA’s standard for public drinking water. In addition, we are providing an opportunity for State and local officials to comment on FDA’s standard of quality for uranium in bottled water in the context of this rulemaking. For the reasons set forth previously in this document, the agency believes that it has complied with all of the applicable requirements under the Executive order.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive order 13132.

### IX. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### X. Effective Date

The agency intends to make the direct final rule effective December 8, 2003.

The agency will publish a confirmation notice for the direct final rule in the **Federal Register** no later than 180 days before the effective date. The agency is providing 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.

### XI. References

1. Hamon, J., “Bottled Water Industry, 2001” Special Industries Spotlight, January 2001. Available at [www.merger.com](http://www.merger.com).
2. Industrial Economics, Inc., *Economic Analysis of the Radionuclides National Primary Drinking Water Regulations*. Available from the Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency. November 2000.
3. Rodwan, J. G., “The 2001 Stat: Bottled Water Sales Reach New Heights,” *Bottled Water Reporter*, p. 14–20, April/May 2002.
4. Eckerman, K., R. Leggett, C. Nelson, J. Pushkin, and A. Richardson, *Cancer Risk Coefficients for Environmental Exposure to Radionuclides*, Federal Guidance Report No. 13, 1999. (EPA 402-R-99-001). Note that FDA used the risk coefficients as adjusted and reported in Ref. 2 of this document in order to be consistent with the EPA radionuclide impact analysis.

### List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

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 adding paragraph (b)(5)(i)(D) and by revising paragraph (b)(5)(ii) to read as follows:

#### § 165.110 Bottled water.

\* \* \* \* \*

(b) \* \* \*

(5) \* \* \*

(i) \* \* \*

(D) The bottled water shall not contain uranium in excess of 30 micrograms per liter of water.

(ii) Analyses conducted to determine compliance with the requirements of paragraph (b)(5)(i) of this section shall