

companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective December 8, 2003. Submit written or electronic comments by May 2, 2003. If FDA receives no significant adverse comments during the specified comment period, the agency will publish a document in the **Federal Register** no later than June 11, 2003, confirming the effective date of the direct final rule. If the agency receives any significant adverse comment during the comment period, FDA intends to withdraw this direct final rule by publication in the **Federal Register** no later than June 11, 2003. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 165.110(b)(5)(ii) as of December 8, 2003.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1640.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 7, 2000 (65 FR 76708), EPA published the Radionuclides Rule to address potential public health effects from the presence of radionuclides in drinking water. This rulemaking finalized a proposed rule that EPA published in the **Federal Register** of July 18, 1991 (56 FR 33050).

Radionuclides are radioactive elements that occur naturally in the Earth's crust or are formed as a result of cosmic ray interactions. Human activities can also add radionuclides to the environment. Radionuclides emit ionizing radiation when they radioactively decay. The potential for harmful health effects from radionuclide exposure results from the ability of ionizing radiation to chemically change molecules that make up biological tissue through a process called ionization. Studies have shown long-term exposure to radionuclides including uranium in drinking water may result in increased risk of cancer and that exposure to uranium can have adverse health effects on kidney function (65 FR 76708 at 76712-76713).

National primary drinking water regulations (NPDWRs) are issued by EPA to protect the public health from the adverse effects of contaminants in drinking water. NPDWRs specify maximum contaminant levels (MCLs) or treatment techniques for drinking water contaminants. In addition, at the same time that it issues NPDWRs, EPA publishes maximum contaminant level goals (MCLGs), which are not regulatory requirements but rather are nonenforceable health goals that are based solely on considerations of protecting the public from adverse health effects of drinking water contamination.

In the Radionuclides Rule, EPA issued an NPDWR containing an MCL for uranium. EPA retained the existing MCLs for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity and indicated the analytical methods it approved for testing for uranium and three other contaminants. Finally, EPA published an MCLG of zero for all radionuclides. EPA's NPDWR has an effective date of December 8, 2003.

Under section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349(b)(1)), 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. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDWR. In addition, section 410(b)(2) of the act provides that a quality standard regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate 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 technique requirements for the same contaminant.

II. Direct Final Rulemaking

FDA has determined that the subjects of this rulemaking are suitable for a direct final rule. The actions taken should be noncontroversial and the agency does not anticipate receiving any significant adverse comment.

FDA is adopting EPA's MCL for uranium as an allowable level in the

quality standard regulation for bottled water. FDA is also retaining the existing allowable levels for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity in the quality standard regulation for bottled water. The existing allowable levels for these radionuclides in bottled water are identical to the existing MCLs for the same radionuclides in drinking water that EPA retained in their Radionuclides Rule. FDA also is specifying analytical methods for determining whether the bottled water is in compliance with the quality standards.

As a consequence of FDA's amending the quality standard for uranium in part 165 (21 CFR part 165), bottled water manufacturers are required to monitor their finished bottled water products for uranium at least once each year (part 129 (21 CFR part 129)). In addition, bottled water manufacturers are required to monitor their source water for uranium at least once every 4 years, unless they meet the criteria for the source water monitoring exemptions under the CGMP regulations (part 129).

If FDA does not receive significant adverse comment on or before May 2, 2003, the agency will publish a notice in the **Federal Register** no later than June 11, 2003, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective December 8, 2003.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or why it would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. A comment recommending a change to the rule that is in addition to the rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of the rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the