

226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity, remains comparable with the quality of public drinking water that meets the Environmental Protection Agency's (EPA's) standards. This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments by May 2, 2003.

ADDRESSES: Submit written comments 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

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The companion proposed rule and the direct final rule are substantively identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and the agency anticipates that it will receive no significant adverse comments. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation notice, after the comment period ends, to confirm the effective date of the direct final rule. The confirmation notice will publish no later than June 11, 2003. FDA intends the direct final rule to become effective December 8, 2003. If FDA receives significant adverse comment, the agency will withdraw the direct final rule. FDA will proceed to respond to all of the comments received regarding the rule, and, if appropriate, the rule will be

finalized under this companion proposed rule using notice-and-comment procedures.

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. Additional Information

For additional information see the corresponding direct final rule published elsewhere in this issue of the **Federal Register**. All persons who wish to submit comments should review the detailed rationale for these amendments set out in the preamble discussion of the direct final rule.

If FDA receives any significant adverse comments regarding this rule, FDA will publish a document withdrawing the direct final rule and will proceed to respond to the comments under this companion proposed rule using usual notice-and-comment procedures.

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. A comment recommending a rule change 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 a 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.

III. EPA Standards

The SDWA, as amended in 1996, requires EPA to publish an NPDWR that specifies either an MCL or a treatment technique requirement for contaminants that may "have an adverse effect on the health of persons," are "known to occur or [have] a substantial likelihood [of occurring] in public water systems with a frequency and at levels of public