

**Federal Register** withdrawing this direct final rule no later than June 11, 2003.

The companion proposed rule, which is in essence identical to the direct final rule, provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments on the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule, and the agency will consider the comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

### 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 health concern," and for which "regulation \* \* \* presents a meaningful opportunity for health risk reduction for persons served by public water systems" (SDWA section 1412(b)(1)(A)). The SDWA (section 300g-l(a)(3)) also requires that EPA issue MCLGs at the same time it issues NPDWRs. MCLGs are nonenforceable health goals that are based solely on considerations of protecting the public from the adverse health effects of contaminants, and not on other considerations, such as potential costs of regulating contaminants and potential technical difficulties of achieving the health goals (59 FR 38668 at 38671). EPA sets MCLs, the enforceable contaminant levels, as close as feasible to the nonenforceable MCLGs.

In its proposed rule on radionuclides (56 FR 33050), EPA proposed comprehensive changes to radionuclides standards in drinking water. However, after conducting a review of costs, benefits, and treatment technologies, in the Radionuclides Rule, EPA established an MCL of 30 micrograms per liter ( $\mu\text{g/L}$ ) for uranium and retained the existing MCLs of 5

picocuries per liter (pCi/L) for combined radium-226/-228, 15 pCi/L for gross alpha (excluding radon and uranium), and 4 millirem (mrem)/year for beta particle and photon radioactivity (65 FR 76708 at 76722).

Because uranium is a kidney toxin as well as a carcinogen, EPA chose an MCL for uranium, expressed in  $\mu\text{g/L}$ , that is protective of both kidney toxicity and carcinogenicity (65 FR 76708 at 76716). Analytical methods approved by EPA for uranium monitoring include activity and mass concentration analyses. If uranium is determined by activity-type methods, a 0.67 pCi/ $\mu\text{g}$  conversion factor is used to convert activity to mass concentration (65 FR 76708 at 76725).

### IV. FDA Standards

#### *A. The Agency's Approach to the Bottled Water Quality Standards Established Under Section 410 of the Act*

Under section 401 of the act (21 U.S.C. 341), the agency may issue a regulation establishing a standard of quality for a food under its common or usual name, when in the judgment of the Secretary of Health and Human Services such action will promote honesty and fair dealing in the interest of consumers. On November 26, 1973 (38 FR 32558), FDA established a quality standard for bottled water that is set forth in § 165.110.

Producers of bottled water are responsible for assuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard (§ 165.110(b)). Bottled water that is of a quality below the prescribed standard is required by § 165.110(c) to be labeled with a statement of substandard quality. Moreover, any bottled water containing a substance at a level that causes the food to be adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) is subject to regulatory action, even if the bottled water bears a label statement of substandard quality.

FDA has traditionally fulfilled its obligation under section 410 of the act to respond to EPA's issuance of NPDWRs by amending the quality standard regulations for bottled water introduced or delivered for introduction into interstate commerce to maintain compatibility with EPA's drinking water regulations. In general, FDA believes that, with few exceptions, EPA standards for contaminants in drinking water are appropriate as allowable levels for contaminants in the quality

standard for bottled water when bottled water may be expected to contain the same contaminants.

FDA generally has not duplicated the efforts of EPA in judging the adequacy of MCLs or treatment techniques in NPDWRs for contaminants when determining their applicability to bottled water in order to protect the public health. FDA believes that, in general, it would be redundant for FDA to reevaluate the drinking water standards prescribed by EPA. Further, because bottled water is increasingly used in some households as a replacement for tap water, consumption patterns considered by EPA for tap water can be used as an estimate for the maximum expected consumption of bottled water by some individuals. Therefore, FDA's view is that generally in cases where bottled water is subject to the same contaminants as tap water, FDA should establish a standard of quality levels in bottled water at the same levels that EPA establishes as MCLs for such contaminants in tap water.

#### *B. Quality Standard for Radionuclides*

The quality standard for bottled water, as set forth in § 165.110(b)(5)(i), prescribes that bottled water shall not contain: (A) combined radium-226/-228 activity in excess of 5 picocuries per liter of water, (B) gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water, and (C) beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year. The quality standard for bottled water, however, does not currently prescribe an allowable level for uranium.

With the exception of uranium, FDA's existing allowable levels for radionuclides (i.e., combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity) in the bottled water quality standard are the same as EPA's existing MCLs for the same radionuclides in drinking water that EPA retained in the Radionuclides Rule. Therefore, FDA will not change the existing allowable levels for these radionuclides in bottled water.