

quality standard for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity in bottled water (65 FR 76708 at 76725). FDA believes that these methods are sufficient to use for determining the level of uranium in bottled water.

#### *D. Monitoring Provisions of CGMP Regulations for Bottled Water*

FDA has established CGMP regulations for bottled water in part 129 (21 CFR part 129). Under § 129.35(a)(3)(i), source water must be analyzed by the plant as often as necessary, but at least once every 4 years for radiological contaminants. Therefore, once the rule becomes effective, bottlers would be required to test their source water as often as necessary but at least once every 4 years for uranium, combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity, unless the bottlers meet the provisions in § 129.35(a)(4) for source water monitoring exemptions. Further, to ensure that a plant's production complies with applicable standards, § 129.80(g)(2) requires radiological analysis by the plant, at least annually, of a representative sample from a batch or segment of a continuous production run for each type of bottled water produced during a day's production. Therefore, once this rule becomes effective, bottlers would be required to test their finished bottled water products at least once a year for uranium, combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity. In addition, bottled water must comply with the allowable levels for radionuclides in the quality standard for bottled water (§ 165.110(b)(5)(i)) unless the label bears a statement of substandard quality under § 165.110(c). As stated in § 165.110(d), bottled water is deemed adulterated if it contains a substance at a level considered injurious to health under section 402(a)(1) of the act.

#### **V. Environmental Impact**

The agency has determined under 21 CFR 25.32(a) 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.

#### **VI. Economic Impact**

##### *A. Initial Regulatory Impact Analysis*

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

##### **1. The Need for Regulation**

In the Radionuclides Rule, EPA published an NPDWR establishing an MCL for uranium. Under section 410 of the act, when EPA issues a regulation establishing an MCL for a contaminant in public drinking water, 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. FDA's standard of quality regulations must also include appropriate monitoring requirements. Of the radionuclide standards addressed in EPA's final rule, only the uranium requirement does not have a current standard of quality regulation for bottled water. If FDA does not issue a standard of quality regulation by 180 days before the effective date of EPA's NPDWRs or make a finding that such a regulation is not necessary to protect the public health, the NPDWRs become applicable to bottled water.

##### **2. Regulatory Options**

FDA considers three options for this analysis:

Option 1. FDA does not establish a uranium quality standard regulation or make a finding that it is not necessary to protect the public health because uranium is not found in water used for bottled drinking water. Bottled water producers would be subject to the requirements set forth in the NPDWR for uranium.

Option 2. FDA establishes a uranium quality standard regulation. Bottled water producers would be subject to allowable levels in § 165.110 and CGMP monitoring requirements in §§ 129.35 and 129.80.

Option 3. Bottled water producers are not subject to either an FDA quality standard regulation or an EPA NPDWR for uranium.

*Note on Option 3:* Since water used for bottled water comes from sources that likely contain some level of naturally occurring uranium, section 410(b)(1) of the act does not allow this option. The act specifies two alternatives: "promulgate a standard of quality regulation under this subsection," or find 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 drinking water." However, the Office of Management and Budget (OMB) cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. Our analysis finds that option 3 does not have the highest net benefits. Therefore, even if option 3 were permissible, the statute does not preclude the option with the highest net benefits.

##### *Assumptions and Estimations Applicable to All Options*

For the purposes of this analysis, FDA makes the following assumptions:

- Option 3, which has zero costs and benefits, will be considered the baseline for this analysis.

- The regulatory options we consider will have no organoleptic effect on the final bottled water product, and thus no impact on sales due to product quality. The cost of the regulation will be limited to the direct cost of testing, recordkeeping, and possible treatment technology investment or other compliance activity.

- Bottled water producers market their products based on meeting government safety testing requirements. However, any change in sales resulting from successful marketing either transfers revenue from one producer to another with no net loss to society, or causes increased sales of bottled water, which would mitigate the cost of this regulatory effort.

- Both the EPA NPDWR and the FDA standard of quality regulations will compel facilities to comply with the