For these reasons, I respectfully concur.

Nora Mead Brownell,

Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 2004N–0416]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its bottled water quality standard regulations by revising the existing allowable level for the contaminant arsenic. As a consequence, bottled water manufacturers would be required to monitor their finished bottled water products for arsenic at least once each year under the current good manufacturing practice (CGMP) regulations for bottled water. Bottled water manufacturers would also be required to monitor their source water for arsenic as often as necessary, but at least once every year unless they meet the criteria for the source water monitoring exemptions under the CGMP regulations. This proposed rule, if finalized, will ensure that the minimum quality of bottled water, as affected by arsenic, remains comparable with the quality of public drinking water that meets the Environmental Protection Agency's (EPA's) standards.

DATES: Submit written or electronic comments by January 31, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0416, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0416 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see section VIII in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer A. Burnham, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2030.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 22, 2001 (66 FR 6976), EPA published the arsenic rule to address potential public heath effects from the presence of arsenic in drinking water. This rulemaking finalized a proposed rule that EPA published in the **Federal Register** of June 22, 2000 (65 FR 38888).

Arsenic is an element that occurs naturally in rocks, soil, water, air, plants, and animals. In addition to the numerous natural sources of arsenic, human activities may also introduce arsenic into food and drinking water. Major present and past sources of arsenic include wood preservatives, agricultural uses, industrial uses, mining and smelting. The human impact on arsenic levels in water depends on the level of human activity, the distance from the pollution sources, and the dispersion and fate of the arsenic that is released. Because arsenic is naturally occurring, the entire population is exposed to low levels of arsenic through food, water, air, and contact with soil. Studies have shown long-term exposure to inorganic arsenic in drinking water may result in increased risk of cancer (e.g., skin, bladder, lung, kidney, liver, prostate, and nasal passage) and is associated with noncancer effects, such as alterations in gastrointestinal, cardiovascular, hematological (e.g., anemia), pulmonary, neurological, immunological, and reproductive/developmental function (66 FR 6976 at 7001 through 7003).

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 arsenic rule, EPA issued an NPDWR containing an MCL of 0.01 milligram per liter (mg/L)[1] or 10 parts per billion (ppb) and an MCLG of zero for arsenic. EPA based the MCL on total arsenic, because drinking water contains almost entirely inorganic forms, and the analytical methods for total arsenic are readily available and capable of being performed by certified laboratories at an affordable cost. EPA's effective date of March 23, 2001, for this rule was temporarily delayed for 60 days to a new effective date of May 22, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan'' (66 FR 7702, January 24, 2001). On May 22, 2001, EPA announced that it would further delay the effective date for the rule until February 22, 2002, to allow time to complete a reassessment of the information on which the revised arsenic standard is based. On February 22, 2002, the arsenic MCL of 0.01 mg/L in public drinking water rule became effective and water systems must comply with the new standard for arsenic in public drinking water by January 23, 2006.

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

[1] As discussed in section II of this document, on March 25, 2003 (68 FR 14502 at 14503), EPA revised the rule text to express the MCL as 0.010 mg/L.

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. 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-1(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). In general, EPA sets MCLs, the enforceable contaminant levels, as close as feasible to the nonenforceable MCLGs.

In its arsenic rule (65 FR 38888), EPA proposed an MCL of 0.005 mg/L and requested comment on the alternate MCLs of 0.003 mg/L, 0.010 mg/L, and 0.020 mg/L for arsenic in drinking water. However, after conducting reanalysis of costs, benefits, and health risk reduction, and factoring in the uncertainties in these analyses and the degree and nature of risk, EPA established an MCL of 0.01 mg/L in the arsenic rule. EPA believed the final MCL of 0.01 mg/L represents the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits and that other regulatory options considered in the proposal did not satisfy the statutory requirements of section 1412(b)(6), Additional Health Risk Reduction and Cost Considerations, of SDWA (66 FR 6976 at 7023).

On March 25, 2003 (68 FR 14502 at 14503), EPA revised the rule text in its January 2001 final rule that established the 10 ppb arsenic drinking water standard to express the standard as 0.010 mg/L, in order to clarify the implementation of the original rule. EPA made this change in response to a concern raised by a number of States and other stakeholders that State laws adopting the Federal arsenic standard as 0.01 mg/L might allow rounding of monitoring results above 0.01 mg/L so that the effective standard (in consideration of rounding of results) would be 0.014 mg/L (or 14 ppb), not 0.010 mg/L (10 ppb).

III. 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 (21 CFR 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 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 Arsenic

The quality standard for bottled water, as set forth in § 165.110(b)(4)(i)(A), prescribes that bottled water shall not contain arsenic in excess of 0.05 mg/L.

FDA has evaluated the MCL for arsenic established by EPA for drinking water. FDA has tentatively concluded that EPA's MCL for arsenic, as a standard of quality level for bottled water, is adequate for the protection of public health. Certain waters used for bottled water may be expected to contain arsenic; thus, FDA believes that adopting EPA's MCL for arsenic will ensure that the quality of bottled water is equivalent to the quality of public drinking water that meets EPA standards.

Therefore, FDA is proposing to establish in § 165.110(b)(4)(iii)(A), which includes allowable levels for inorganic substances, an allowable level for arsenic at 0.010 mg/L and remove the existing entry for arsenic in § 165.110(b)(4)(i)(A).

C. Analytical Methods for Arsenic

In the arsenic rule, EPA listed the analytical methods that it had approved for use by public water systems to determine compliance with the arsenic MCLs (66 FR 6976 at 6988 to 6989). Therefore, FDA is proposing in new § 165.110(b)(4)(iii)(E)(*14*) to incorporate by reference EPA approved analytical methods (66 FR 6976 at 6988) for determining compliance with the quality standard for arsenic in bottled water. FDA believes that these methods

are sufficient to use for determining the level of arsenic in bottled water.

D. Monitoring and Recordkeeping 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 a minimum frequency of once each year for chemical contaminants. Bottlers would be required to test their source water as often as necessary, but at least once each year for arsenic, 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 chemical 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. Under § 129.80(h), records of analytical test results for contaminants shall be maintained at the plant for not less than two years and shall be available for official review at reasonable times. Therefore, once this rule becomes effective, bottlers would be required to test their finished bottled water products at least once a year for arsenic and maintain a record of the arsenic test results for at least two years. In addition, bottled water must comply with the allowable levels for arsenic in the quality standard for bottled water (§ 165.110(b)(4)(iii)(A)) 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.

IV. 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.

V. Economic Impact

A. 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, public 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. Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

1. Need for Regulation

In the **Federal Register** of January 22, 2001 (66 FR 6976), EPA published a final rule on arsenic in drinking water. This rulemaking finalized a proposed rule that EPA published in the **Federal Register** of June 22, 2000 (65 FR 38888). Under section 410 of the act, when EPA issues a regulation establishing an MCL for a particular contaminant in drinking water, we are required to issue a standard of quality regulation governing that contaminant in bottled water or make a finding that such a regulation is unnecessary to protect the public health. Our quality standard must also include appropriate monitoring requirements. If we do not issue a quality standard for arsenic in bottled water by 180 days before the effective date of EPA's NPDWR or make a finding that such a regulation is not necessary to protect the public health, then EPA's regulation becomes applicable to bottled water as well as drinking water.

We are proposing to amend the quality standard for arsenic in bottled water rather than taking no action to allow EPA's NPDWR for arsenic to become applicable to bottled water because the costs and benefits of requiring any given maximum arsenic level may be different for bottled water than for drinking water. For detailed information on FDA's objectives, legal basis, and compliance requirements for this rule, see section III in the **SUPPLEMENTARY INFORMATION** of this document.

2. Regulatory Options

We considered five regulatory options in this analysis:

- Reestablish a quality standard for arsenic in bottled water that maintains the current allowable level of 0.05 mg/L.
- Take no action. Under this option, EPA's regulation on arsenic in drinking water would become applicable to bottled water.
- Establish a quality standard for arsenic in bottled water that adopts EPA's MCL for arsenic in drinking water of 0.010 mg/L. Under this option, bottled water producers would be subject to CGMP monitoring requirements in §§ 129.35 and 129.80.
- Establish a quality standard for arsenic in bottled water that sets the allowable level of arsenic at 0.02 mg/L.
- Establish a quality standard for arsenic in bottled water that sets the allowable level of arsenic at 0.005 mg/L.

We request comments on any other reasonable regulatory option that we may have overlooked.

Data and Assumptions Applicable to all Options

(1) The Dun's Market Identifiers database lists 378 establishments under North American Industry Classification System (NAICS) code 312112 Bottled Water Manufacturing. This corresponds to 318 firms after restricting establishments to headquarters, ultimate locations, or single establishments (Ref. 1).

(2) We assume that the regulatory options we consider will not affect the organoleptic qualities of bottled water and thus will not reduce the value that consumers place on bottled water. The cost of the regulation will be limited to the direct cost of abatement, monitoring, and other compliance activity.

(3) We request comments on our estimate of the benefits and costs generated by the various regulatory options and on the assumptions and data on which we have based our estimates.

Option One—Reestablish a quality standard for arsenic in bottled water that maintains the current allowable level of 0.05 mg/L. We consider this option to be the baseline for this analysis. Therefore, by convention, we define the costs and benefits of this option to be zero. Usually, we define the baseline to be the option of taking no action because it implies the continuation of the current regulatory environment. However, in this case, taking no action implies a change in the regulatory environment because it would mean that EPA's drinking water regulations would be applied to bottled water.

Option Two—Take no action.

Benefits of Option Two

If we take no action, then EPA's regulations governing arsenic in drinking water would become applicable to bottled water. EPA

characterized the benefit of their regulation revising the MCL for arsenic in drinking water in terms of a reduction in adverse health effects and a reduction in the need for consumers to take relatively costly steps, such as purchasing bottled water, to reduce their exposure to arsenic. According to EPA's analysis, epidemiological studies have found that arsenic ingestion is associated with an increased risk of cancer and a variety of other adverse health effects. The relevant forms of cancer include skin, liver, bladder, kidney, and lung. The other adverse health effects include cardiovascular, pulmonary, immunological, neurological, endocrine, reproductive, and developmental effects (Ref. 2). However, EPA was only able to find sufficient information to quantify the benefits associated with reductions in the incidence of bladder and lung cancer. We have also limited our quantified estimate of benefits to these two types of cancer because we have also not found any information that would allow us to quantify the benefits from reducing other types of adverse health effects.

Cases of Cancer Avoided

Exposure. EPA estimated the mean daily average per capita consumption of community drinking water in the United States to be 1 L/person/day and the mean daily average per capita consumption of total water, which includes bottled water, to be 1.2 L/person/day. Therefore, EPA found that bottled water represents approximately 17 percent of the mean daily average per capita consumption of water from all sources (Ref. 3).

Risk and valuation of risk. EPA estimated the number of bladder and lung cancer cases that they will eliminate by reducing the MCL for arsenic in drinking water from 0.05 mg/L to 0.010 mg/L. The lower bound of their estimated range of cases did not include exposure to arsenic in bottled water, but the upper bound did include exposure to arsenic in bottled water. We extrapolated the number of cancer cases that would be eliminated if EPA's regulations were applied to bottled water using EPA's estimates for total water and bottled water consumption. We multiplied EPA's upper bound estimate by 17 percent ([0.2 L/person/day bottled water consumption]/[1.2 L/person/day total water consumption]), and we multiplied their lower bound estimate by 20 percent ([0.2 L/person/day bottled water consumption])/[(1.2 L/person/day total water consumption - 0.2 L/person/day bottled water]). Under this approach, we estimate that applying EPA's arsenic regulations to bottled water would eliminate between 4.3 and 5.1 fatal cases of cancer per year and between 3.2 and 4.4 nonfatal cases of cancer per year. We used a range of $5 to $6.5 million for the value of a statistical life (VSL) to value this reduction in health risks. This range includes the VSL of $6.1 million that EPA used in their analysis. We used EPA's estimate of $607,162 for the value of avoiding a nonfatal case of bladder or lung cancer. Applying these values to our estimated range of eliminated adverse events, we estimate that the benefit of applying EPA regulations to bottled water would be $23 to $36 million per year.

Sensitivity analysis. EPA considered a number of other factors in a sensitivity analysis. These factors included various potential latency periods for the relevant types of cancer (5, 10, or 20 years), the growth of income over the latency period using a range of income elasticity of demand for the willingness to pay to reduce the risk of death of between 0.22 and 1.0, discounting over the latency period (3 and 7 percent), and corrections for differences in voluntariness and controllability of the risks from arsenic in water and the risks that formed the basis of their VSL. The income elasticity of demand for willingness to pay to reduce risk of death is the percent increase in willingness to pay to reduce risk of death for every 1 percent change in income. Accounting for these issues results in an adjusted VSL of $1.72 to $6.25 million (Ref. 4). The low end of the range is based on a latency period of 20 years, adjusting for the growth of income over the latency period at an income elasticity of 0.22, discounting at 7 percent over the latency period, and adjusting for differences in voluntariness and controllability. The high end of the range is based on a latency period of 5 to 20 years (no effect on estimate) with only an adjustment for income growth over the latency period at an income elasticity of 1.0. The low end of the adjusted range of VSL falls outside the range of $5 to $6.5 million that we used for the VSL in the previous section. Expanding the range of estimated benefits to incorporate this adjusted lower bound results in a range of estimated benefits of $9 to $36 million per year.

Costs of Option Two

Abatement. In order to estimate abatement costs, we must first estimate the number of bottled water establishments producing water having arsenic levels over EPA's revised MCL of 0.010 mg/L. EPA estimated that 5.3 percent of community water systems using ground water sources produce water with arsenic levels higher than 0.010 mg/L (Ref. 5). Most bottled water establishments obtain their water from either a community water system or a ground water system (66 FR 16858 at 16863; March 28, 2001). Bottled water establishments using community water systems would be using water that falls under EPA's drinking water regulations irrespective of our findings on bottled water. If the water systems were not in compliance with EPA's regulations, then the bottled water establishments might need to take steps to bring the water into compliance with EPA regulations. However, in the long run, abatement costs should devolve onto the community water system. We do not know how many bottled water establishments using community water systems would need to take short-term abatement action on their own behalf. About 75 percent of bottled water establishments use water that does not come from a community water system (66 FR at 16863, March 28, 2001). The cost for bottled water firms using community water systems will probably be lower than the costs for bottled water firms using ground water sources because community water systems generally already will be in compliance with EPA's drinking water regulations. However, to simplify the analysis, we have based our estimated costs on the assumption that all bottled water establishments use ground water sources. Based on EPA's estimate of arsenic levels in ground water sources used by community water systems, we assume that 5.3 percent of bottled water establishments currently use source water with arsenic levels higher than 0.010 mg/L. Based on these assumptions and estimates, we estimate that 20 bottled water establishments would face additional arsenic abatement costs if EPA's regulations revising the MCL for arsenic to 0.010 mg/L were applied to bottled water.

EPA's analysis estimated the annual costs associated with thirteen different methods of reducing arsenic to a level of 0.010 mg/L based on the initial arsenic concentration and the size of the water system involved, defined in terms of the number of people served by that system (Ref. 6). We have insufficient information to determine how many of the affected bottled water establishments would adopt each of the potential treatment methods. If any establishments could choose any treatment method, then we would base our cost estimate on the least costly treatment method. However, there may be technical reasons why a given establishment cannot adopt certain

treatment methods or cannot adopt them at the costs estimated by EPA. Therefore, we have used the average cost across all treatment methods. EPA reported cost results for two different initial arsenic concentrations: 0.011 mg/L and 0.050 mg/L. We do not know the distribution of initial concentrations of arsenic in bottled water establishments. We have used these two initial concentrations to estimate a range of treatment costs. We present our cost estimates in table 1 of this document. The annual costs are based on annualizing one time costs using an interest rate of 7 percent over 20 years and adding the annual costs. The costs are reported in 1999 dollars. Rounding to the nearest million, we estimate abatement costs to be approximately $7 to $11 million per year.

TABLE 1.—ABATEMENT COSTS

Number of Establishments	Annual Cost Per Establishment	Total Annual Cost
20	$565,925	$11,337,739
20	$366,758	$7,347,620

Testing. In order to consider the incremental change resulting from EPA's testing requirements, we must consider current testing requirements. Our current regulations require bottled water establishments to analyze source water for arsenic as often as necessary to ensure compliance with the maximum allowable level of arsenic but at least once per year, unless the establishments meet the provisions in § 129.35(a)(4) for source water monitoring exemptions. The exemptions most relevant to arsenic testing allow establishments using community water systems to use the test results or compliance certifications from those systems in lieu of testing the source water themselves and allow firms that do not use public water systems as the source of their water to reduce the frequency of testing if they can document that such a reduction is consistent with a State-issued waiver under EPA regulations. As we discussed previously in this document, our cost estimates are based on the simplifying assumption that all bottled water establishments use ground water sources rather than community water systems. Therefore, we have not adjusted the estimated number of tests because of the exemption for establishments that use community water systems. We do not know how many bottled water establishments currently face reduced testing requirements because they are able to document that such a reduction is consistent with a State-issued waiver under EPA regulations. However, it is unlikely that all establishments qualify for such a waiver. Therefore, we assume that between 0 and 90 percent of bottled water establishments obtain waivers in any given year and will therefore not need to test source water for arsenic in that year. Finally, we assume that establishments that do not meet the exemption test for arsenic once per year. In addition to source water testing, we also require bottled water establishments to analyze at least once a year a batch or segment of a continuous production run for each type of bottled water produced during a day's production. We assume that each bottled water establishment produces only one type of bottled water. Based on these assumptions, we estimate that bottled water establishments collectively run 416 to 756 tests for arsenic per year.

EPA's drinking water regulations require ground water systems to test for arsenic once every 3 years. If a test shows a violation, then that system must test for arsenic once every 3 months until the State determines that the system is reliably and consistently below the MCL for arsenic or until the system installs treatment technology. However, States can only determine that a ground water system is reliably and consistently below the MCL if that system has taken at least two samples at 3-month intervals. We do not know how many bottled water establishments might fail a test and need to take additional tests, nor do we know how many additional tests beyond the mandatory two such tests States would require before allowing such establishments to resume testing once every 3 years. We estimated above that 5.3 percent of firms would need to take abatement action to reduce arsenic levels to 0.010 mg/L. However, we expect that most bottled water establishments in any given year would pass the required tests. Therefore, we assume that between 0 and 10 percent of establishments that do not have waivers will be testing on a 3-month basis during a given year. In addition, under EPA's regulations, bottled water establishments would be able to apply for a 9-year waiver from the testing requirements, which the States may grant if the establishment demonstrates adequate source water protection by completing a vulnerability assessment and also demonstrates that three previous samples were below the maximum contaminant level. We do not know how many bottled water establishments will request waivers and how many of those waivers States will grant. However, it is unlikely that all establishments would qualify for such a waiver. Therefore, we assume that between 0 and 90 percent of facilities will obtain a waiver and will therefore not need to test for arsenic in a given year. The remaining facilities that do not have waivers will be testing on a 3-year basis. Based on these assumptions, we estimate that bottled water establishments would collectively run approximately 5 to 101 tests for arsenic per year under EPA's regulation. Therefore, we estimate that adopting EPA's regulations would result in the elimination of between 163 and 745 tests per year.

Finally, EPA regulations require that ground water systems must begin testing by the end of 2007. Therefore, if EPA regulations were to become effective for bottled water at the end of 2004, then bottled water establishment would have a 3-year period during which they would not be required to test for arsenic by either us or EPA.

For community water systems, EPA assumed that collecting a sample and reporting a sample would each require 1 hour of the system operator's time. EPA estimated the hourly rate of the system operator to be approximately $15 for systems serving less than 3,000 customers. EPA also assumed that all systems are already equipped to collect samples, so that no system would need to install taps, repipe wells, or take other actions to make sampling possible. Finally, EPA assumed that systems would utilize one of two laboratory methods: (1) Stabilized temperature platform graphite furnace atomic absorption (STP–GFAA) or (2) graphite furnace atomic absorption (GFAA) (Ref. 7). They estimated that both techniques cost $40 per sample. Therefore, they found the cost per sample to be approximately $70. We assume that

bottled water establishments would face similar monitoring costs.

Based on the difference in the current testing requirements under our regulations and EPA's drinking water regulations, we estimate that if EPA's regulations on arsenic in drinking water became applicable to bottled water it would reduce arsenic testing costs by $30,000 to $53,000 per year for the first 3 years and by $11,000 to $52,000 for every year thereafter. These costs reductions round to $0 when rounded to the nearest million.

State monitoring costs. EPA also discussed monitoring costs accruing to States for recording test sample results, issuing violation letters, and reviewing waiver applications. EPA estimated that for community water systems serving less than 10,000 customers, States would require 1 hour to record a testing result, 4 hours to issue a violation letter, and 8 hours to review a waiver application. In all cases, EPA estimated the relevant wage rate to be $41.47 per hour. We estimated the enforcement costs if States were to enforce EPA's arsenic regulations for bottled water establishments based on EPA's costs estimates for community water systems and our estimate of the number of tests, violative tests, and waiver applications that would be generated by these establishments, which we discussed in the preceding section. However, for the number of waiver applications, we assumed that only one-ninth of the establishments that we assumed would be operating under an approved 9-year waiver in any given year actually applied for that waiver in that year. Under these assumptions, we assume State enforcement costs would be approximately $500 to $29,000 per year. This cost rounds to $0 when rounded to the nearest million.

Administrative costs. EPA also estimated administrative costs relating to establishing and maintaining the programs necessary to comply with the revised arsenic standard and the new monitoring requirements. For community water systems having fewer than 10,000 customers, EPA estimated that water system employees would spend 8 hours on reading and understanding the rule and 16 hours on training employees to comply with the rule. Again, EPA estimated an average hourly wage of $15.03 for the employees of such systems. Applying these cost estimates to 378 bottled water establishments results in an estimated one-time administrative cost of approximately $137,000. This cost rounds to $0 million.

EPA also estimated one-time administrative costs for State activity such as developing and adopting State regulations that meet the new Federal arsenic requirements and training community water systems in the new regulations. EPA estimated these costs on the basis of full-time equivalents (FTEs), which they assumed to cost $64,480, including overhead and fringe benefits. EPA estimated that States would require 0.2 FTEs for regulation adoption and program development, 0.5 FTEs for system training and technical assistance for both community water systems and ''non-transient non-community water systems,'' and 0.12 FTEs for system staff training. We have assumed that States would face comparable costs in developing a system to apply EPA's regulations to bottled water establishments. However, we have adjusted the total FTEs to include systems training and technical assistance for just one category of entities, which in this case is bottled water establishments. Under these assumptions, one-time State administrative costs would be approximately $4 million.

Public notification costs. EPA regulations require community water systems to prepare and distribute public notifications of water analyses. EPA did not analyze the costs of these requirements in their analysis of their final rule on arsenic in drinking water because they already require community water systems to provide these analyses. However, if EPA's regulations were to be applied to bottled water establishments, then bottled water establishments would also need to prepare and send out public notifications of water analyses. It is not clear how EPA would adapt these regulations to bottled water establishments because such establishments do not have a simple way to identify their customers for purposes of sending out public notifications. Therefore, we have not attempted to quantify this cost.

Total Costs and Benefits of Option Two

Based on the preceding analysis, we estimate that taking no action and allowing EPA's arsenic regulations to become applicable to bottled water would generate quantified benefits of $9 to $36 million per year, quantified costs of $11 to $15 million in the first year and $7 to $11 million in every year after the first year, plus any costs associated with public notification requirements.

Option Three—Establish a quality standard for arsenic in bottled water that adopts EPA's MCL for arsenic in drinking water of 0.010 mg/L.

If we establish a quality standard regulation for arsenic in bottled water that adopts EPA's revised MCL for arsenic in drinking water but maintains our testing requirements and enforcement mechanisms, then we would maintain the quantified benefits of $9 to $36 million per year and the abatement costs of $7 million to $11 million that we estimated for Option Two. In addition, this option would generate some additional testing costs for firms that fail to meet the level of 0.010 mg/L but that would have met the level of 0.05 mg/L. These additional testing costs would probably only take place during the initial transition period from 0.05 mg/L to 0.010 mg/L. Once firms adopt abatement procedures and establish the effectiveness of those procedures, then annual testing costs would probably be similar to current testing costs. We do not have sufficient information to estimate how many additional tests this option might generate. However, based on an estimated cost of $70 per sample that we discussed under Option Two, any additional testing costs would probably be small.

Option Four—Establish a quality standard for arsenic in bottled water that sets the allowable level of arsenic at 0.02 mg/L.

Benefits. Using the same approach that we used in Option Two, but applying EPA's benefits estimates for a revised MCL of 0.02 mg/L, we estimate that this option would eliminate between 1.9 and 2.0 fatal cases of cancer per year and between 1.5 and 1.7 nonfatal cases of cancer per year. This corresponds to a quantified benefit between $4 to $14 million per year under the expanded range of adjusted VSL estimates that we discussed in the sensitivity analysis section of Option Two.

Costs. EPA did not provide detailed cost estimates for an MCL of 0.02 mg/L; therefore, we cannot estimate costs using the same approach that we used in Option Two. However, EPA's estimate of the total abatement costs under this option was 36 percent of the estimated total abatement costs under an MCL of 0.010 mg/L (Ref. 8). If this relationship held for bottled water, then the abatement costs of this option would be $3 to $4 million per year. In addition, this option would generate some additional testing costs for firms that fail to meet the level of 0.02 mg/L but that would have met the level of 0.05 mg/L. These additional testing costs would probably only accrue during the initial transition period from 0.05 mg/L to 0.02 mg/L. Once firms adopt abatement procedures and establish the effectiveness of those procedures, then annual testing costs would probably be

similar to current testing costs. We do not have sufficient information to estimate how many additional tests this option might generate. However, any additional testing costs would probably be small.

Option Five—Establish a quality standard for arsenic in bottled water but that sets the allowable level of arsenic at 0.005 mg/L.

Benefits. Using the same approach that we used in Option Two, but applying EPA's benefits estimates for a revised MCL of 0.005 mg/L, we estimate that this option would eliminate between 5.8 and 9.1 fatal cases of cancer per year and between 4.4 and 7.9 nonfatal cases of cancer per year. This corresponds to a quantified benefit of $13 to $64 million per year under the expanded range of adjusted VSL estimates that we discussed in the sensitivity analysis section of Option Two.

Costs. EPA did not provide detailed cost estimates for an MCL of 0.005 mg/L; therefore, we cannot estimate costs using the same approach that we used in Option Two. However, EPA's estimate of the total abatement costs under this option was 233 percent of the estimated total abatement costs under an MCL of 0.010 mg/L (Ref. 8). If this relationship held for bottled water costs, then the abatement costs of this option would be $17 to $26 million. In addition, this option would generate additional testing costs for firms that fail to meet the level of 0.005 mg/L but that would have met the level of 0.05 mg/L. These additional testing costs would probably only accrue during the initial transition period from 0.05 mg/L to 0.005 mg/L. Once firms adopt abatement procedures and establish the effectiveness of those procedures, then annual testing costs would probably be similar to current testing costs. We do not have sufficient information to estimate how many additional tests this option might generate. However, any additional testing costs would probably be small.

Summary of Benefits and Costs for Regulatory Options

We present a summary of the estimated costs and benefits in table 2 of this document. Option 3 (adopting EPA's MCL) appears to generate higher net benefits than either maintaining the current allowable level of arsenic in bottled water of 0.05 mg/L or taking no action and allowing EPA's regulations to become applicable to bottled water. The estimated net benefits of adopting an allowable level of 0.010 mg/L overlaps with the estimated benefits of adopting an allowable level of 0.05 mg/L. The lower end of the range of potential net benefits is higher for 0.010 mg/L, but the higher end of the range is higher for 0.05 mg/L.

TABLE 2.—SUMMARY OF COSTS AND BENEFITS ($ MILLIONS)

Option	Cost	Benefit	Net Benefit
Option 1—Maintain 0.05 mg/L	Baseline	Baseline	Baseline
Option 2—Take no action	$11 to $15 in first year, $7 to $11 every year after first year, plus public notification costs	$9 to $36 plus unquantified benefits	-$6 to $25 minus notification costs plus unquantified benefits in first year, $4 to $33 minus notification costs plus unquantified benefits in subsequent years
Option 3—Adopt 0.010 mg/L	$7 to $11	$9 to $36 plus unquantified benefits	-$2 to $29 plus unquantified benefits
Option 4—Adopt 0.02 mg/L	$3 to $4	$4 to $14 plus unquantified benefits	$0 to $11 plus unquantified benefits
Option 5—Adopt 0.005 mg/L	$17 to $26	$13 to $64 plus unquantified benefits	-$13 to $47 plus unquantified benefits

B. Small Entity Analysis

We have examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this rule would have a significant economic impact on a substantial number of small entities.

We discussed the compliance costs that bottled water establishments would face as a result of proposing to amend the quality standard regulation for arsenic in bottled water in the Regulatory Impact Analysis section of this document. In this Small Entity Analysis section, we discuss in greater detail the impact of the proposed regulatory action on small entities.

The Small Business Administration's definition of a small business for NAICS code 312112 Bottled Water Manufacturing is an entity with 500 or fewer employees. Under this definition, 82 percent of the bottled water firms (260 of 318) identified in the Dun's Market Identifiers database are small firms (Ref. 1). Therefore, this rule would affect small bottled water manufacturers.

A trade magazine listed a preliminary estimate of total producer revenues for all U.S. bottled water manufacturers in 2003 of $8,277 million (Ref. 9). According to this magazine, the top five bottled water firms accounted for 69 percent of total wholesale dollar sales in 2003. This suggests that 31 percent of total revenue, or $2,566 million, accrues to firms other than the five largest firms. We do not know the portion of this revenue that accrues specifically to small firms. If the revenue of the 53 large firms other than the five largest firms were similar to the revenue of the 260 small firms, then each small firm would have annual revenue of $8.2 million. However, the revenue per firm of the large firms other than the five largest firms is probably greater than the revenue per firm of the small firms; so many small firms probably have annual revenue of less than $8.2 million. The 1997 economic census also has some information relevant to estimating the revenue of small firms. A Census report based on this data suggests that the value of shipments per establishment for all establishments with less than 500 employees ranged from approximately $0.6 million to $20.5 million in 1997

(Ref. 10). To calculate this range, we subtracted the total value of shipments of all the establishments in the size categories for which the Census report provided value of shipment information from the total value of shipments for firms of all sizes to obtain the value of shipments of the establishments in the size categories for which the Census report did not provide value of shipments information. We then divided the resulting value by the number of establishments in the size categories for which the Census report did not produce value of shipments information. The Census report provided information on value of shipments based only per establishment. We do not know the average number of establishments per small firm; however, most small firms probably consist of only one establishment. The Census report did not provide information on revenue by establishment size. However, value of shipments is a reasonable proxy for revenue. Therefore, the estimate of the value of shipments per small establishment is probably a reasonable estimate of the revenue per small firms.

We do not know the profit rates of small firms. According to one account, the median profit rate across all Fortune 500 firms in 2000 was approximately 5 percent (Ref. 11). If we assume a profit margin of between 1 percent and 10 percent, then each small firm would have annual profit of between approximately $0.01 million and $2.1 million.

We do not have sufficient information to estimate the proportion of industry compliance costs that would be borne by small firms. In the preceding regulatory impact analysis, we estimated that 20 establishments would need to undertake arsenic abatement action if we chose Option 3, and we estimated that each establishment would face compliance costs of approximately $0.4 million to $0.6 million, based on EPA's cost estimates for community water systems. These 20 establishments might belong to either large or small firms. Again, we assume that most small firms probably consist of only one establishment. Therefore, we estimate that 0 to 20 small firms would face compliance costs of approximately $0.4 million to $0.6 million per year. Thus, some small firms may face annual compliance costs that exceed estimated annual profits or that represent a considerable portion of estimated annual profits.

To investigate the potential significance of these impacts, we entered these costs into a model prepared for us under contract by ERG. [Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses and its Application to Four FDA-Regulated Industries. Final. July 12, 2002.] The model is designed to estimate the percentage of small firms that would go out of business (i.e., go from a positive cash flow to a negative cash flow) because of given compliance costs if those costs accrued to all small firms in a given industry. However, these results can also be interpreted as the probability that any given small firm that faces those compliance costs will go out of business. According to this model, an annual cost of $0.4 million would generate a 56 percent probability that a small firm with less than 20 employees that faced those costs would go out of business and a 10 percent probability that any firm with 20 to 499 employees that faced those costs would go out of business, if the distribution of cash flow across firms fits the normal distribution. Similarly, an annual cost of $0.6 million would generate a 67 percent probability that a small firm with less than 20 employees that faced those costs would go out of business and a 14 percent probability that any firm with 20 to 499 employees that faced those costs would go out of business, if cash flow across firms fits the normal distribution. Thus, the model suggests that these costs could have a significant impact on some firms under certain conditions. Therefore, in the absence of more detailed information on the distribution of revenues and costs and the profit margins of small firms, we find that this rule might have a significant economic impact on a substantial number of small entities. We request comments and information on the annual revenue and profit margins of small bottled water manufacturers and on the impact of this rule on those firms. We also request comments on our approach to estimating costs, which we discussed in the regulatory impact analysis under Option 2.

The primary regulatory option that would reduce the burden on small firms would be to allow them to produce bottled water with a higher allowable level of arsenic than we allow larger firms to produce. This would reduce yearly abatement costs, which represent most of the compliance costs of this rule. We could also reduce the number or frequency of tests that we require such firms to perform. However, that would have only a minor impact on estimated costs. In the preceding regulatory flexibility analysis, we considered the option of setting the allowable level of arsenic in bottled water to 0.02 mg/L rather than the proposed 0.01 mg/L. We estimated that this option would reduce total compliance costs to a range of $3 million to $4 million per year. However, we did not discuss the number of establishments that would face these costs. EPA estimated that 2.0 percent of community water systems using ground water sources produce water with arsenic levels higher than 0.02 mg/L. (Ref. 5) We assumed in the regulatory impact analysis that all bottled water firms used ground water systems. Under this assumption, 2.0 percent of bottled water establishments, or 8 establishments, currently use source water with arsenic levels higher than 0.02 mg/L. Therefore, we estimate that 0 to 8 small firms would face compliance costs of approximately $0.4 million to $0.5 million per year. These per firm costs remain significant in relation to estimated per firm profits. The reduction in the impact on small firms under this option occurs because fewer small firms would face these costs.

However, allowing small firms to produce bottled water with a higher level of arsenic than we allow larger firms to produce might also reduce benefits. If all 20 of the establishments that we estimated would need to take abatement action to meet an allowable arsenic level of 0.01 mg/L were small firms, then setting the allowable arsenic levels for small firms to 0.02 mg/L would reduce benefits by the full amount that we discussed in the regulatory impact analysis in the context of setting the allowable arsenic levels for all firms to 0.02 mg/L rather than 0.01 mg/L. Specifically, it would reduce estimated benefits from a range of $9 million to $36 million plus unquantified benefits to a range of $4 million to $14 million plus unquantified benefits. On the other hand, if none of the 20 establishments that we estimated would need to take abatement action to meet an allowable arsenic level of 0.01 mg/L were small firms, then setting the allowable arsenic levels for small firms to 0.02 mg/L would have no impact on benefits. In that case, small firms would also face no compliance costs. We request comments on any other reasonable alternative that would reduce the burden of this rule on small entities.

We have not been able to identify any Federal rules that duplicate, overlap or conflict with the proposed rule. We currently regulate arsenic levels in bottled water. If we were to take no action, EPA's NPDWR for arsenic would apply to bottled water.

C. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year.'' We have determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VI. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized as proposed, would have 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(a)(1) of the act 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 proposed rule, if finalized as proposed, will have preemptive effect in that it would preclude States from issuing requirements for arsenic levels in bottled water that are not identical to the allowable level for arsenic as set forth in this proposed 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 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 January 22, 2001, EPA issued an NPDWR containing an MCL for arsenic (66 FR 6976). FDA has determined that the MCL for arsenic that EPA established for public drinking water is appropriate as a standard of quality for bottled water, and is issuing this proposed regulation consistent with section 410 of the act.

Further, section 4(e) of the Executive order provides that ''when an agency proposes 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 arsenic in public drinking water provided notice of possible FDA action for a standard of quality for arsenic in bottled water. FDA did not receive any correspondence from State and local officials regarding an arsenic standard for bottled water subsequent to EPA's NPDWR on the MCL for arsenic. Moreover, FDA is not aware of any States that have requirements for arsenic in bottled water that would be affected by FDA's decision to establish a bottled water quality standard for arsenic 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 arsenic 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.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comment, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. Effective Date of the Related Final Rule

The agency intends to make any final rule based on this proposal effective January 23, 2006. The agency will publish a confirmation document for a 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.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Puro, E., Memo to the Record, June 22, 2004.

2. Arsenic in Drinking Water Rule Economic Analysis, Abt Associates Inc. for U.S. Environmental Protection Agency, EPA 815–R–00–026, pp. 5–7, December 2000. Available on the internet on November 15, 2004, at *http://www.epa.gov/safewater/ars/econ_analysis.pdf*.

3. Ibid. pp. 5–9.

4. Ibid. Exhibit 5–12, pp. 5–30.

5. Ibid. Exhibit 4–10, pp. 4–12.

6. Ibid, pp. 6–1 to 6–38.

7. Ibid. pp. 6–14.

8. Ibid. Exhibit 6–10, pp. 6–28.

9. Rodwan, J. G., ''Solid Gains Put Bottled Water in No. 2 Spot,'' *Bottled Water Reporter*, p. 17, April/May 2004.

10. Bottled Water Manufacturing, 1997 Economic Census Manufacturing Industry Series, EC97M–3121B, 1997, U.S. Census Bureau, U.S. Department of Commerce, table 4, p. 9.

11. Drug industry most profitable, survey. CNBC and the Wall Street Journal-Businesses, November 30, 2001.

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, it is proposed that 21 CFR part 165 be 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 removing the entry for ''Arsenic'' in the table in paragraph (b)(4)(i)(A), by revising paragraph (b)(4)(iii)(A) and the introductory text of paragraph (b)(4)(iii)(E), and by adding paragraph (b)(4)(iii)(E)(*14*) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(4) * * *

(iii) * * *

(A) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter (or as specified)
Arsenic	0.010.
Antimony	006.
Barium	2.
Beryllium	0.004.
Cadmium	0.005.
Chromium	0.1.
Copper	1.0.
Cyanide	0.2.
Lead	0.005.
Mercury	0.002.
Nickel	0.1.
Nitrate	10 (as nitrogen).
Nitrite	1 (as nitrogen).
Total Nitrate and Nitrite	10 (as nitrogen).
Selenium	0.05.
Thallium	0.002.

* * * * *

(E) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(A) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(E)(*1*) through (b)(4)(iii)(E)(*14*) of this section and described, unless otherwise noted, in ''Methods for Chemical Analysis of Water and Wastes,'' U.S. EPA Environmental Monitoring and Support Laboratory (EMSL), Cincinnati, OH 45258 (EPA–600/4–79–020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

(*14*) Arsenic shall be measured using the following methods:

(*i*) Method 200.8—''Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectroscopy,'' contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples—Supplement 1,'' EPA/600/R–94/111, May 1994, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from NTIS, PB95–125472, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(*ii*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Platform Graphite Furnace Atomic Absorption Spectrometry,'' contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples—Supplement 1,'' EPA/600/R–94/111, May 1994, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*14*)(*i*) of this section.

* * * * *

Dated: October 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26531 Filed 11–26–04; 4:44 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05–04–209]

RIN 1625–AA09

Drawbridge Operation Regulations; Elizabeth River-Eastern Branch, Norfolk, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulations that govern the operation of the Norfolk Southern (NS) Railroad Bridge (NS #V2.8) across Eastern Branch of the Elizabeth River, at mile 2.7, in Norfolk, VA. The proposed change would allow the NS #V2.8 bridge to be operated from a remote location, and to be operated from a remote location, and to remain open for vessel traffic and only close for train crossings and periodic maintenance. This proposed rule would make the operation of the bridge more efficient, because currently the bridge only opens on signal, or on signal after notice.

DATES: Comments and related material must reach the Coast Guard on or before January 18, 2005.

ADDRESSES: You may mail comments and related material to Commander (obr), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704–5004. The Fifth