et seq.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by the OMB under control numbers 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 58 minutes to prepare and submit form BIS–748. Miscellaneous and recordkeeping activities account for 12 minutes per submission.

Burden hours associated with the Paperwork Reduction Act and Office and Management and Budget control number 0694–0088 are not impacted by this regulation. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to David Rostker, OMB Desk Officer, by e-mail at *david_rostker@omb.eop.gov* or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (*see* 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et. seq.,* are not applicable.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

■ Accordingly, BIS adopts, without change, the interim final rule published at 70 FR 10865, March 7, 2005 as a final rule.

Dated: June 3, 2005.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 05–11418 Filed 6–8–05; 8:45 am]

BILLING CODE 3510–33–P

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its bottled water quality standard regulations by revising the existing allowable level for the contaminant arsenic. As a consequence, bottled water manufacturers are 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 are also 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 final rule 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: This rule is effective January 23, 2006. 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 21 CFR 165.110(b)(4)(iii), as of January 23, 2006.

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 a final rule issuing a National Primary Drinking Water Regulation (NPDWR) containing a maximum contaminant level (MCL) of 0.01 milligram per liter (mg/L) or 10 parts per billion (ppb) and a Maximum Contaminant Level Goal (MCLG) of zero for arsenic 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). 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. On March 25, 2003 (68 FR 14501 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).

Under section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349(b)(1)), FDA is required to issue a standard of quality regulation for a contaminant in bottled water 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), 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.

In accordance with section 410 of the act, FDA published in the **Federal**

Register of December 2, 2004 (69 FR 70082), a proposal to adopt EPA's MCL for arsenic as an allowable level in the quality standard for bottled water. In the 2004 proposal, FDA tentatively concluded that the MCL that EPA had established based on available toxicological information for arsenic in public drinking water was adequate for the protection of public health. 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 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. Interested persons were given until January 31, 2005, to submit comments.

II. Comment on the Proposed Rule

FDA received four letters, each containing one or more comments, in response to the December 2, 2004, proposal. The comments were received from two trade associations and two consumers. Two letters generally support the proposal with one containing comments suggesting modifications to various provisions of the Analysis of Economic Impacts section. The agency's responses to these suggestions are addressed in that section. Two letters raised issues that are outside the scope of this rulemaking (the appropriate agency to regulate bottled water and EPA's requirements for testing frequency) and therefore are not addressed here.

III. Conclusion

The agency is adopting the allowable level for arsenic in the quality standard for bottled water as proposed (69 FR 70082). Therefore, FDA is establishing in § 165.110(b)(4)(iii)(A) (21 CFR 165.110(b)(4)(iii)(A)), which includes allowable levels for inorganic substances, an allowable level for arsenic at 0.010 mg/L and removing the existing entry for arsenic in § 165.110(b)(4)(i)(A).

With respect to analytical methods for the determination of chemical contaminants, FDA is making the following changes in § 165.110(b)(4)(iii). In the new § 165.110(b)(4)(iii)(E)(14), FDA is incorporating by reference EPA approved analytical methods (66 FR 6975 at 6988) for determining compliance with the quality standard for arsenic in bottled water. These methods are contained in the manual entitled ''Methods for the Determinations 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 source for this manual containing the two methods is the National Technical Information Service (NTIS), PB95–125472, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161. FDA believes that these methods are sufficient to use for determining the level of arsenic in bottled water.

Therefore, upon the effective date of this rule, January 23, 2006, any bottled water that contains arsenic at a level that exceeds the applicable allowable level will be deemed misbranded under section 403(h)(1) of the act (21 U.S.C. 343(h)(1)) unless it bears a statement of substandard quality as provided by § 165.110(c)(3).

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (69 FR 70082, December 2, 2004). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the economic implications of this final 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. The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

This final regulatory impact analysis revises the analysis set forth in the proposed rule (69 FR 70082) in response to comments received. Except as we indicate below, the analysis in this final rule is the same as the analysis of the proposed rule.

1. Need for Regulation

We did not receive any comments on the discussion of the need for regulation in the analysis of the proposed rule. To briefly summarize the discussion in the analysis of the proposed rule, under section 410 of the act, when the Environmental Protection Agency (EPA) issues a regulation establishing an MCL for a particular contaminant in 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 unnecessary to protect the public health. FDA's quality standard must also include appropriate monitoring requirements. If FDA does not issue a quality standard for arsenic in bottled water by 180 days before the effective date of EPA's regulations 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.

2. Regulatory Options

We considered five regulatory options in the analysis of the proposed rule:

Option One—Re-establish a quality standard for arsenic in bottled water that maintains the current allowable level of 0.05 mg/L.

Option Two—Take no action. Under this option, EPA's regulation on arsenic in drinking water would become applicable to bottled water.

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. Under this option, bottled water producers would be subject to CGMP monitoring requirements in 21 CFR 129.35 and 129.80.

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

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

One comment stated that bottled water should be regulated by EPA, not FDA. This comment maintained that economies of scale suggest that EPA should oversee bottled water as well as tap water and that it is wasteful for us to spend public money to change bottled water regulations in a way that mirrors EPA's regulations for tap water.

This option is outside the scope of this rulemaking and would not be legally feasible at this time. In addition, changing the jurisdiction of bottled water from FDA to EPA would generate costs in addition to cost savings. We do not have information suggesting that the net benefits of this option would be likely to be greater than the net benefits of the options that we considered in the proposed rule. Therefore, we have not addressed this option in this analysis.

3. General Comments

(Comment 1) One comment argued that some bottled water establishments may need to purify their water using reverse osmosis or other methods in order to meet an allowable level of 0.010 mg/L. This comment suggested that these establishments would need to change the identification of their products from ''spring water'' to ''purified water.'' The comment noted that this could lead to a loss of utility for consumers who prefer spring water if they have limited choices for home or office water delivery and can no longer obtain spring water from other establishments. Finally, the comment noted that this change in how consumers value bottled water could reduce sales for the establishments producing that water, although the comment noted that that it was unable to estimate this cost.

(Response) The comment is correct that if bottled water establishments need to adopt treatment methods that require them to change the identity of their product, (e.g., from ''spring water'' to ''purified water'') then some consumers might place a lower value on that water. If some consumers choose not to continue to consume the water after the identity change, then some bottled water establishments could face a decline in sales and profits. We would classify any loss of profit from shifts in consumer demand as a distributive impact rather than a social cost because the sales and profit losses for some firms would be offset by countervailing sales and profit increases for other firms. The comment did not provide sufficient information to estimate the loss in consumer utility or the distributive impact on industry. Although the comment only discussed this effect in relation to an allowable level of 0.010 mg/L (corresponding to Options 2 and 3), the same effect might also be relevant to any reduction in the current allowable level of 0.05 mg/L, including reductions to allowable levels of 0.02 mg/L (Option 4) and 0.005 mg/L (Option 5). The likelihood of this effect would be greater the lower the allowable level. Thus, this effect would be largest under Option 5 and smallest under Option 4.

(Comment 2) One comment suggested that our estimate of the benefits of specifying a maximum arsenic level of 0.005 mg/L was too high because EPA based their benefit estimate on a flawed interpretation of the available data, and we based our benefit estimate on EPA's benefit estimate. This comment cited a report issued by the National Academy of Sciences (NAS) that the comment claimed concluded that arsenic does not cause bladder or lung cancer at levels up to 0.05 mg/L (50 ppb) in drinking water (Ref. 1). Although the comment made this point in relation to our benefit estimates for Option 5 (allowable level of 0.005 mg/L), it is also relevant to our benefit estimates for Options 2 and 3 (allowable level of 0.01 mg/L) and Option 4 (allowable level of 0.02 mg/L). The comment also argued that EPA based its risk assessment on extrapolating cancer risks from relatively high levels of arsenic investigated in some epidemiological studies to the relatively low levels that EPA considered when setting an MCL for arsenic. According to the comment, the NAS study highlighted the uncertainty associated with this extrapolation and also suggested there might be a threshold below which arsenic in water would not increase the risk of cancer at all. The comment noted that EPA reviewed this study prior to issuing a regulation establishing a MCL of 0.01mg/L. Finally, the comment cited an article that was published after EPA's regulation that reportedly found no association between bladder cancer and arsenic in drinking water at a level of 0.10 mg/L and another article that ostensibly made a similar point.

(Response) The 2001 NAS study concluded that arsenic in drinking water increases the risk of bladder or lung cancer at concentrations at least as low as 0.003 mg/L (Ref. 2). Although the study noted that a threshold was theoretically possible, it noted that there was no experimental data to identify a threshold and concluded that any threshold was likely to occur below concentrations that are relevant to the U.S. population (Ref. 3). The study did note that there was insufficient mode-of-action data on arsenic to provide a biological basis for using either a linear or nonlinear extrapolation to estimate low dose health risks and that the choice of extrapolation method was, in part, a policy decision (Ref. 4). However, the study supported the use of a linear extrapolation in conjunction with a discussion of the uncertainties associated with that approach (Ref. 5). EPA acknowledged uncertainty about the impact of reducing arsenic to the levels under consideration in this rule and carried out a sensitivity analysis to reflect that uncertainty. The range of potential benefits that we estimated in the proposed rule reflects that uncertainty. However, EPA could not have considered the two articles cited in the comment that were published after the publication of the regulation. One of these articles found no increase in the risk of bladder cancer from arsenic in drinking water at levels up to 0.1 mg/L (Ref. 6). The other article found no increase in the risk of death from bladder cancer from arsenic in drinking water at concentrations between 0.003 mg/L and 0.06 mg/L (Ref. 7). We based our benefit estimates on reductions of bladder cancer and lung cancer. EPA's estimated health benefit from reductions in bladder cancer were approximately 30 percent of the total health benefits from reductions in both bladder and lung cancer. Therefore, we have reduced the lower bound of our estimated range of benefits to reflect the possibility that none of the options under consideration reduce the risk of bladder cancer.

4. Option One—Re-establish a Quality Standard for Arsenic in Bottled Water That Maintains the Current Allowable Level of 0.05 Mg/L

We used this option as the baseline in the analysis of the proposed rule. We did not receive any comments on the use of this option as the baseline. We did receive one comment that noted that an allowable level of 0.05 mg/L might not lead to the same health benefits as an allowable level of 0.01 mg/L. This observation is consistent with the analysis of the proposed rule in which we attributed health benefits to moving from the baseline to an allowable level of 0.01 mg/L.

5. Option Two—Take No Action

Benefits of option two.

(Comment 3) One comment from a trade group that stated it represented 270 bottled water establishments argued that we may have overestimated the benefits of taking no action and allowing EPA's regulations governing arsenic in drinking water to become applicable to bottled water. The trade group that submitted this comment stated that it has required its members to meet a maximum arsenic level of 0.010 mg/L (10 ppb) since 2002 as a condition of membership. The comment also noted that California's Department of Health Services established a standard of quality specifying an allowable level of 0.01 mg/L (10 ppb) for arsenic in bottled water in 2000. This comment argued that most medium and

large bottled water establishments of ''natural water'' belong to this trade group or sell water in California. Finally, the comment noted that approximately 25 percent of the bottled water sold in the United States is ''purified water'' and that most purified water is produced using the reverse osmosis method, which removes a substantial amount of any existing arsenic from the final product. The comment concluded that the vast majority of bottled water sold in the United States already meets an allowable level of 0.010 mg/L and that any potential health benefits from revising the allowable level of arsenic from 0.05 mg/L to 0.01 mg/L may have already been realized.

(Response) In the analysis of the proposed rule, we based our benefit estimates on EPA's analysis of its drinking water regulations. EPA's analysis found that 5.3 percent of the ground water sources used by community water systems failed to meet a maximum arsenic level of 0.010 mg/L. We used the same percentage as the percentage of bottled water establishments that would fail to meet that level of arsenic. Thus, our benefit estimate accounted for the fact that the vast majority of bottled water establishments use water that already meets a maximum arsenic level of 0.010 mg/L. The 270 establishments that this comment stated belonged to the trade group in question represent 73 percent of the 370 establishments that we identified in the analysis of the proposed rule. Thus, the information provided by the comment is consistent with the 5.3 percent estimate.

Abatement.

(Comment 4) One comment argued that some bottled water establishments might not be able to choose some of the 13 abatement methods that EPA discussed in their analysis. The comment noted that we used the average cost of these abatement methods in our analysis. According to this comment, establishments that bottle natural water containing naturally occurring arsenic may face abatement costs substantially higher than the average of the 13 methods discussed in the EPA report because of the commercial and financial restraints on their ability to selectively remove arsenic while maintaining the standard of identity for natural water. The comment also noted that abatement costs would depend on the initial level of arsenic found in the water (e.g., reductions from 0.03 mg/L to 0.01 mg/L is more expensive than reductions from 0.02 mg/L to 0.01 mg/L).

(Response) We acknowledged in the analysis of the proposed rule that some bottled water establishments might be unable to use some of the 13 potential abatement methods EPA discussed in their analysis. Our rationale for using the average cost of those methods was that some establishments might be able to use the less expensive methods while other establishments might need to use the more expensive methods. Using average cost is appropriate in this context because we are estimating total costs rather than the costs that any particular facility might face. The comment did not provide sufficient information to revise this approach. EPA's cost estimates, on which we based our cost estimates, accounted for the fact that abatement costs depend on the initial level of arsenic in the water.

Testing.

(Comment 5) One comment argued that we overstated the potential benefit from reduced testing costs under this option and suggested that this option would probably not reduce testing costs at all. This comment noted that we estimated that adopting this option would eliminate between 163 and 745 tests per year. The comment said that such a reduction is highly unlikely because bottled water establishments that sell bottled water in more than one State might need to apply for waivers for each State in which they sell their product but may be unable or unwilling to pay for multiple waivers. The comment also noted that some States regulate bottled water as a food product and require annual testing for contaminants including arsenic. The comment said that only two of the States that regulate bottled water as food offer testing waivers for bottled water. In addition, the authors of the comment noted that they were unaware of any State granting a bottled water establishment a 9-year waiver for any contaminant. The comment claimed that adopting EPA's testing schedule for arsenic could result in additional tests because EPA's testing schedule would not coincide with States' testing schedules. Finally, the comment noted that the delay in testing requirements that we discussed in the analysis of the proposed rule would probably not affect bottled water establishments that operate in States that regulate bottled water as a food.

(Response) In the analysis of the proposed rule, we assumed that between 0 and 90 percent of bottled water establishments might operate under a waiver in any given year. The low end of this range is consistent with the comment's assertion that few bottled water establishments would be able or willing to obtain waivers. The comment provided some reasons why the upper bound of 90 percent may be unrealistically high, but it did not provide an alternative upper bound estimate. The comment also did not provide sufficient information to estimate any additional testing that the comment claimed could be required under this option because of discrepancies between EPA's testing schedule and States' testing schedules, or the additional cost of tracking EPA's testing schedule if it differs from States' testing schedules, or the proper adjustment for the start of our testing requirements to account for the fact that some establishments must test annually because of State regulations. In the analysis of the proposed rule, we estimated that the change in testing costs generated by this option would round to $0 million per year. Attempting to further refine this estimate to account for these factors would have little effect on the overall results.

(Comment 6) One comment argued that we failed to include some of the costs associated with testing requirements under this option. This comment noted that we previously allowed EPA regulations on maximum levels for nine other contaminants in drinking water to become effective for bottled water. The nine contaminants were antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8–TCDD (dioxin). The comment argued that implementing EPA testing requirements for these contaminants created confusion and inconsistencies because EPA designed their testing requirements for municipal water systems rather than for bottled water establishments. The comment suggested that this experience showed that implementing EPA testing requirements for arsenic would also create confusion about testing requirements for bottled water establishments.

(Response) We are not addressing previous actions regarding the nine contaminants in this analysis. However, experiences generated by past actions may be relevant to this analysis. In this case, the comment claims that past experience suggests that adapting EPA's testing requirements for bottled water establishments could create some initial confusion. However, the comment did not provide sufficient information to allow us to quantify this cost. Therefore, we have added this cost as an unquantified cost.

Administrative costs.

We did not receive any significant comments on this section.

Public notification.

(Comment 7) One comment noted that we said that under this option (i.e., if we take no action and EPA's regulations are applied to bottled water establishments according to section 410 of the act) EPA's requirement that community water systems prepare and distribute public notifications of water analyses might apply to bottled water establishments, but we were unsure how EPA would apply or adapt these public notification requirements to bottled water establishments. The comment argued that if we take no action, then EPA's public notification requirements for community water systems would not become applicable to bottled water establishments and that the only change in our current regulations would be that EPA's MCL for arsenic and testing requirements would replace the existing maximum arsenic level and testing requirements. In addition, the comment noted that bottled water would remain under our jurisdiction.

(Response) If we take no action, then EPA's NPDWR for arsenic in public drinking becomes applicable to bottled water. In addition to MCLs and monitoring requirements, EPA's NPDWRs (40 CFR part 141) contain other requirements such as analytical requirements (e.g., use of certified labs), reporting (e.g., test results submitted to the states), public notification (e.g., consumer confidence reports), and recordkeeping (chemical test results to be kept for at least 10 years). As such, EPA's public notification requirements would be applicable to bottled water. However, we agree with the comment that bottled water would remain under our jurisdiction and that we would be responsible for enforcing EPA's public notification requirements for bottled water establishments.

Total costs and benefits of option two.

Based on the analysis of the proposed rule and the preceding discussion, we estimate that taking no action and allowing EPA's NPDWR for arsenic to become applicable to bottled water would generate quantified benefits of $6 to $36 million per year (revised from $9 to $36 million per year in the analysis of the proposed rule), 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, any costs associated with potential confusion associated with adapting EPA's testing requirements and any loss of consumer utility associated with product identity changes. This option could also cause some firms that produce bottled spring water to lose profits and firms producing competing products to increase profits.

6. 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

(Comment 8) One comment noted that one advantage of this option is that the vast majority of bottled water establishments would not need to change their current testing procedures and States could easily harmonize their regulations with FDA regulations.

(Response) This option would maintain current testing requirements and would therefore probably not disrupt existing testing schedules or otherwise create confusion about monitoring requirements. We did not attribute these costs to this option in the analysis of the proposed rule.

7. Option Four—Establish a Quality Standard for Arsenic in Bottled Water That Sets the Allowable Level of Arsenic at 0.02 Mg/L

We did not receive any significant comments on this section.

8. 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.

We discussed the only comment that we received on the benefits of this option (that some bottled water establishments may need to purify their water and change the identification of their products from ''spring water'' to ''purified water'' to meet this requirement) in the preceding section entitled General Comments because that comment was relevant to all of the options.

Cost.

(Comment 9) One comment noted that this option would affect more establishments than would Option 2 because this option involves a lower allowable level for arsenic. The comment suggested that this would generate a further increase in costs that is unknown but could be substantial.

(Response) We estimated the costs of this option by adjusting our cost estimate for Option 2 upward by 232 percent based on the change in EPA's estimate of overall abatement costs associated with MCLs of 0.005 mg/L and 0.01 mg/L. EPA's cost estimate accounted for the fact that a MCL of 0.005 mg/L would affect more community water systems than would a MCL of 0.01 mg/L. Thus, our estimate already indirectly accounted for an increase in the number of affected establishments under this option.

Summary of benefits and costs for regulatory options.

We present a summary of our revised cost and benefit estimates in table 1 of this document. Option 3 (adopting EPA's allowable arsenic level) appears likely 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 NPDWR for arsenic to become applicable to bottled water. The estimated net benefits of adopting an allowable level of 0.010 mg/L overlap significantly with the estimated net benefits of adopting an allowable level of 0.005 mg/L. The lower end of the range of potential net benefits is substantially higher for 0.010 mg/L, but the higher end of the range is substantially higher for 0.005 mg/L.

Table 1.—Summary of Costs and Benefits ($ millions)

Option	Cost	Benefit	Net Benefit
Option 1–Maintain 0.05 mg/L	Baseline	Baseline	Baseline

Table 1.—Summary of Costs and Benefits ($ millions)—Continued

Option	Cost	Benefit	Net Benefit
Option 2–Take no action	$11 to $15 in first year, $7 to $11 every year after first year, plus public notification costs, any costs associated with potential confusion associated with adapting EPA testing requirements, and any loss of consumer utility associated with product identity changes	$6 to $36 plus unquantified health benefits	-$9 to $25 plus unquantified benefits minus unquantified costs in first year, -$5 to $29 plus unquantified benefits minus unquantified costs in subsequent years
Option 3–Adopt 0.010 mg/L	$7 to $11, plus any loss of consumer utility associated with product identity changes	$6 to $36 plus unquantified health benefits	-$5 to $29 plus unquantified benefits minus unquantified costs
Option 4–Adopt 0.02 mg/L	$3 to $4, plus any loss of consumer utility associated with product identity changes	$3 to $14 plus unquantified benefits	-$1 to $10 plus unquantified benefits minus unquantified costs
Option 5–Adopt 0.005 mg/L	$17 to $26, plus any loss of consumer utility associated with product identity changes	$9 to $64 plus unquantified benefits	-$17 to $47 plus unquantified benefits minus unquantified costs

B. Small Entity Analysis

We have examined the economic implications of this final 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.

In the analysis of the proposed rule, we discussed allowing small firms to produce bottled water containing a higher level of arsenic than larger firms as one possible approach to reducing the burden on small firms.

(Comment 10) One comment argued that such an approach would provide less protection to consumers and would be difficult to communicate to consumers. The comment suggested that we instead consider delaying the effective date of the rule for small businesses.

(Response) We acknowledged the impact on benefits that would occur if we allowed small firms to produce bottled water containing a higher level of arsenic than larger firms in the analysis of the proposed rule. We did not discuss the difficulty of communicating the existence of different maximum arsenic levels to consumers. However, this cost is not an additional cost but an alternative to the health costs that we discussed in the Small Entity Analysis section of the proposed rule. If we successfully communicated the existence of different arsenic levels to consumers, then consumers would presumably choose bottled water with lower levels of arsenic, and we would not expect to see a decline in health benefits. We do not have sufficient information to evaluate the cost or effectiveness of educating consumers on different arsenic levels as an alternative or partial alternative to the health costs of allowing small firms to produce bottled water containing more arsenic than bottled water produced by larger firms. Delaying the effective date for small firms would delay the onset of abatement costs but would not otherwise reduce those costs. Delaying costs would reduce the present value of those costs due to discounting. However, delaying the effective date would also delay the onset of the corresponding health benefits.

(Comment 11) One comment argued that some bottled water establishments may need to purify their water using reverse osmosis or other methods in order to meet a maximum arsenic level of 0.010 mg/L. This comment suggested that some of these methods would require those establishments to change the identification of their products from ''spring water'' to ''purified water.'' The comment noted that this might change how consumers value the water and could reduce sales for the firms producing that water. The comment noted that it was unable to estimate this cost. We discussed this comment in the preceding impact analysis of this document. However, this comment is also relevant to this section because it noted that any loss of profit was more likely to affect smaller firms than larger firms because smaller bottlers have more limited treatment options and distribution areas.

(Response) The comment is correct that any changes in product identity that might take place if bottled water establishments found it necessary to adopt certain treatment methods might lead to changes in how consumers value the water and could reduce sales and profits for some small firms. The comment did not provide sufficient information to estimate this potential impact on small firms.

VI. Paperwork Reduction Act

FDA concludes that this final 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 final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has 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) 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 rule has pre-emptive 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 rule, this pre-emptive 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. 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 final 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 or in response to FDA's proposed rule (69 FR 70082, December 2, 2004) to adopt EPA's MCL for arsenic as an allowable level in the quality standard for bottled water. 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. 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 pre-emptive effects of the final rule are consistent with Executive Order 13132.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Arsenic in Drinking Water: 2001 Update, National Academy Press, Washington, DC, 2001, available on the Internet at *http://www.nap.edu/books/0309076293/html/*.

2. Ibid., p. 13.

3. Ibid., pp. 6–7, 11.

4. Ibid., pp. 6, 11.

5. Ibid., p. 11.

6. Steinmaus, C., Yuan, Y., Bates, M.N., et al., 2003, ''Case-Control Study of Bladder Cancer and Drinking Water Arsenic in the Western United States,'' *American Journal of Epidemiology*, 158(12):1193–1201.

7. Lamm, S., Engel, A., Kruse, M., et al., 2004, ''Arsenic in Drinking Water and Bladder Cancer Mortality in the United States: An Analysis Based on 133 U.S. Counties and 30 Years of Observation,'' *Journal of Occupational and Environmental Medicine*, 46(3):298–306.

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, 21 CFR part 165 is 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*) as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(4) * * *

(iii) * * *

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

Contaminant	Concentration in milligramsper 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 National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

* * * * *

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

(*i*) Method 200.8—''Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry,'' Revision 5.4, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.8 is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples—Supplement 1,'' EPA/600/R–94/111, May 1994. Copies of this publication are available from the National Technical Information Service (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 National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*ii*) Method 200.9—''Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption,'' Revision 2.2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.9 is contained in the manual entitled ''Methods for the Determination of Metals in Environmental Samples—Supplement 1,'' EPA/600/R–94/111, May 1994. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*14*)(*i*) of this section.

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Dated: May 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11406 Filed 6–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 39

RIN 1076–AE54

Conforming Amendments To Implement the No Child Left Behind Act of 2001

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: This final rule renumbers certain sections of 25 CFR part 39 in order to conform to the amendments published on April 28 and to rationalize the number system in part 39. It also eliminates two obsolete cross references.

DATES: Effective June 9, 2005.

FOR FURTHER INFORMATION CONTACT: Catherine Freels, Designated Federal Official, PO Box 1430, Albuquerque, NM 87103–1430; Phone 505–248–7240; e-mail: *cfreels@bia.edu*.

SUPPLEMENTARY INFORMATION: On April 28, 2005, the Department published in the **Federal Register** (70 FR 22178) the final rule implementing the No Child Left Behind Act of 2001 (the Act). The April 28 rule revised subparts A through H of part 39, while leaving subparts I through L unaffected. Although subparts I through L were unchanged by publication of the April 28 rule, the section numbers used in those subparts were used for some of the sections in the revised subparts A through H. Through an unintentional oversight, the Department did not renumber the sections of subparts I through L to eliminate duplication. This rectifies this oversight by renumbering all sections in subparts I through L in order to remove potential conflicts from Title 25. It also removes two obsolete cross references.

Compliance Information

1. *Regulatory Planning and Review (E.O. 12866).* This document is not a significant rule and the Office of Management and Budget has not reviewed this rule under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This rule does not raise novel legal or policy issues. It makes only changes necessary to ensure that these sections of 25 CFR conform to the changes made by the new rule being published in final today.

2. *Regulatory Flexibility Act.* The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regualtory Flexibility Act (5 U.S.C. 601 *et seq.*).

3. *Small Business Regulatory Enforcement Fairness Act (SBREFA).* This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

4. *Unfunded Mandates Reform Act.* This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. The rule makes only changes necessary to ensure that these sections of 25 CFR conform to the changes made by the new rule being published in final today.

5. *Takings (E.O. 12630).* In accordance with Executive Order 12630, the rule does not have significant takings