DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Final Rule to Revise the Allowable Level of Fluoride in Bottled Water to which Fluoride Has Been Added

Docket No. FDA-2018-N-1815

Economic Analysis of Impacts

Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated one-time costs to read and understand the rule as well as to verify fluoride levels following adjustment to their manufacturing process will be up to $776 per firm, or approximately 0.004 percent of the average annual value of shipments for a small bottled water manufacturer, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The rule revises the bottled water quality standard for the allowable level for fluoride to a maximum of 0.7 milligrams per liter (mg/L) in bottled water to which fluoride has been added, a level consistent with the updated U.S. Public Health Service (PHS) recommendations for the optimal level of fluoride in community water systems to prevent dental caries (tooth decay). The current allowable levels range 0.8–1.7 mg/L, depending on annual average outdoor air temperatures. There may be some health benefits from revising this standard for fluoride in bottled water. As stated in the 2011 Department of Health and Human Services (HHS) notice proposing the revised recommended fluoride concentration, available data suggest that a concentration of 0.7 mg/L provides an optimal balance between the prevention of dental caries and the risk of dental fluorosis (76 FR 2383 at 2386). Moreover, this may reduce any unnecessary confusion on the part of consumers from having the standard for fluoride added to bottled water differ from the PHS recommendations for community water fluoridation. The rule may also reduce regulatory uncertainty by simplifying the standard to a single maximum concentration independent of average air temperatures. There may be some cost savings for bottled water manufacturers that add fluoride to their bottled water products from adding less fluoride to bottled water to which fluoride is added.

There will be one-time costs to read and understand the rule for all bottled water manufacturers and one-time costs to verify the fluoride level after adjustment of the manufacturing process for bottled water manufacturers that choose to add fluoride to their product. The one-time costs range between $214,370.26 and $333,338.24. When discounted at seven percent over 10 years, the annualized costs range from $30,521.50 and $47,459.87. When

discounted at three percent over 10 years the annualized costs range from $25,130.73 to $39,077.41.

In Table 1, we present the total benefits, costs, and distributional effects of this rule.

Table 1: Economic Data: Costs and Benefits Statement

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified					7%		Improved balance between the risks of dental caries and dental fluorosis
						3%		
	Qualitative	Adopt current PHS recommendations. There may be some changes to the risks of dental fluorosis and dental caries. There may also be some reduction in confusion by consumers from having the standard for fluoride added to bottled water differ from the PHS recommendations. The rule may also reduce regulatory uncertainty from simplifying the standard to a single maximum concentration. There may be cost savings from manufacturers adding less fluoride to bottled water to which fluoride is added.						
Costs	Annualized Monetized $millions/year	$0.039	$0.031	$0.047	2020	7%	10 years	
		$0.032	$0.025	$0.039	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
		From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
		From:			To:			
Effects	State, Local or Tribal Government: No effect Small Business: No effect Wages: No estimated effect Growth: No estimated effect							

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

Our proposed rule to amend the quality standard for bottled water to set the allowable level for fluoride at 0.7 mg/L in domestically packaged and imported bottled water to which fluoride has been added published in the *Federal Register* of April 3, 2019 (84 FR 12975). In this section, we summarize and respond to the comments that we received on the Preliminary Economic Analysis of Impacts.

(Comment 1)

One comment states that the costs for learning the rule and for verifying fluoride levels in bottled water would be one-time costs based on a domestic assumption, but that for imported bottled water, the proposed fluoride level, if finalized, would have no positive economic effects.

(Response 1)

We stated in the Preliminary Economic Analysis of Impacts that there would be one-time costs to learn the rule for all bottled water manufacturers and one-time costs to verify the fluoride level after adjustment of the manufacturing process for bottled water manufacturers that choose to add fluoride to their product. Thus, the analysis applied to *all* manufacturers – domestic and foreign. The comment provided, and we are aware of, no new data that would impact our analysis. Therefore, we use the same data and come to the same conclusions in our Final Economic Analysis of Impacts.

Regarding the positive economic effects of the rule, we provided a cost analysis in our Preliminary Economic Analysis of Impacts, and noted that one-time costs ranged between $129,802.42 and $224,554.41. We noted the proposed rule, if finalized, would generate some benefit from continued prevention of dental caries while minimizing the potential risk of dental fluorosis, and that making consistent the standards for added fluoride between bottled water and

community water systems may reduce potential consumer confusion about the level of fluoride in the water they consume. The comment provided, and we are aware of, no new data that would change our analysis.

(Comment 2)

One comment states that in order to reach a fluoride level of 0.7 mg/L in bottled water, FDA would incur a one-time cost of between $129,802.42 and $224,554.41. However, the comment claims that according to the National Institutes of Health, the cost of a full mouth dental reconstruction was $9,349 and that there were approximately 1.5 million full mouth dental reconstructions per year. Therefore, the costs of full mouth dental reconstruction and dental caries prevention are near the one-time costs to change fluoride levels. Consequently, the comment concludes that updating the allowable level of fluoride is beneficial from an economic perspective.

(Response 2)

While we appreciate the information on the cost of a full mouth dental reconstruction, we note that consumers may undergo full mouth dental reconstruction for reasons besides tooth decay, and that this rule is lowering the allowable level, but does not require fluoride to be added to bottled water. We summarized the benefits of the rule in our Preliminary Economic Analysis of Impacts, noting that (1) available data suggest that a fluoride concentration of 0.7 mg/L in water provides an optimal balance between the prevention of dental caries and the risk of fluorosis, and (2) the proposed level may reduce any unnecessary confusion on the part of consumers from having the standard for fluoride added to bottled water differ from the PHS recommendations for community water fluoridation. The costs, on the other hand, are one-time costs to learn the rule for all bottled water manufacturers and one-time costs to verify the fluoride

level after adjustment of the manufacturing process for bottled water manufacturers that choose to add fluoride to their product. The comment provided, and we are aware of, no new data that would change our analysis.

D. Summary of Changes

We have updated the costs of reading and understanding the rule using 2020 wages obtained from the Department of Labor, Bureau of Labor Statistics (Ref. 1) and inflated the costs to verify the fluoride level after adjustment of the manufacturing process to 2020 dollars using the Consumer Price Index. We have also made explicit our assumption that the domestic and foreign costs of the rule are the same. In addition, we have added the "Purpose of the Rule" and "Analysis of Regulatory Alternatives" sections consistent with our template for regulatory impact analyses, and have made non-substantive clarifications and edits to the Introduction and Benefits sections and elsewhere for ease of reading.

II. Final Economic Analysis of Impacts

A. Background

Dental fluorosis is caused by taking in too much fluoride over a long period when the teeth are forming under the gums. Dental fluorosis is a condition that causes changes in the appearance of tooth enamel. It may result when children regularly consume fluoride during the teeth-forming years. Children aged 8 years and younger are at increased risk of dental fluorosis because their permanent teeth are still forming (Ref. 2). Most dental fluorosis in the U.S. is very mild to mild, appearing as white spots on the tooth surface that may be barely noticeable and do not affect dental function. Severe forms of dental fluorosis, which are far less common, cause

more extensive enamel changes. In the rare, severe form, pits may form in the teeth. Dental caries are prevalent throughout the population. The Centers for Disease Control and Prevention (CDC) reports that approximately 91 percent of U.S. adults aged 20-64 had dental caries in permanent teeth in 2011-2012 (Ref. 3). The PHS recommends the optimum level of fluoride in community water systems that combats dental caries in the population without aggravating the risks of dental fluorosis.

In 1973 we published a final rule promulgating a standard of quality for bottled water that set the allowable levels of fluoride in bottled water. The fluoride limitations were taken directly from the 1962 PHS Drinking Water Standards which are intended to achieve a concentration at which significant caries prevention benefits can be achieved and risk of fluorosis reduced. The 1962 PHS standard recommends that the concentration be kept within the lower control limits, which ranged from 0.6 mg/L to 0.9 mg/L, and the upper control limits which ranged from 0.8 mg/L to 1.7 mg/L. In 2015, the PHS published a final recommendation notice that updated and replaced the 1962 Standards related to community water fluoridation (Ref. 4). The PHS now recommends the optimal fluoride concentration of 0.7 mg/L for community water systems.

HHS updated the 1962 PHS Drinking Water Standards related to community water fluoridation based on (1) scientific evidence related to effectiveness of water fluoridation on caries prevention and control across all age groups, (2) fluoride in drinking water as one of several available fluoride sources, (3) trends in the prevalence and severity of dental fluorosis, and (4) current evidence on fluid intake in children across various outdoor air temperatures. The updated PHS recommendation is an optimal fluoride concentration of 0.7 mg/L when added to community water systems (Ref. 4). Based on the evidence, the PHS recommends this

concentration level as the one that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis.

On April 27, 2015, we issued a letter to industry recommending that bottled water manufacturers do not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L (Ref. 5). In our letter, we also stated our intent to revise the allowable levels for fluoride in bottled water to which fluoride has been added to be consistent with the updated PHS recommendation.

B. Market Failure or Other Social Purpose Requiring Federal Regulatory Action

The final rule addresses an institutional failure. Without revising the appropriate standard for bottled water to which fluoride is added, some bottled water might have levels of added fluoride inconsistent with PHS recommendations for community water fluoridation.

Updating our bottled water quality standard to align with the recommendation for community water systems that add fluoride would ensure consistency with the PHS recommendations. To the extent that bottled water manufacturers continue current practices based on the outdated 1962 Drinking Water Standards, we have created an institutional failure by not updating our bottled water standards. The final rule corrects this institutional failure which will also reduce any confusion on the part of consumers regarding levels of fluoride in bottled water to which fluoride is added.

C. Purpose of the Rule

The purpose of the rule is to amend the allowable levels for fluoride in bottled water to which fluoride is added, to be consistent with the updated recommendation by the PHS on the

optimal fluoride concentration in community water systems that add fluoride for the prevention of dental caries.

D. Baseline Conditions

An internal analysis of data from the 2013-2016 National Health and Nutrition Examination Surveys (NHANES) indicates a significant fraction of per capita water consumed alone as a beverage comes from bottled water sources (about 39 percent overall and about 43 percent for children 8 years of age and under) (Ref. 6).

In addition, information from our Food Facility Registration Module (FFRM) indicates there were 669 domestic bottled water manufacturing establishments subject to an inspection between 2002 and 2016. These include establishments that were both inactive and seasonal as well as establishments that manufacture bottled water year-round. Food facility registration data covering FY2015 and most of FY2016 indicates that US consumers have purchased imported bottled water from approximately 1,340 foreign manufacturing establishments. Consequently, we estimate there would be 2,009 foreign and domestic bottled water establishments affected by the final rule (669 + 1,340 = 2,009). Industry information suggests that no more than 3 percent of bottled water manufacturers add fluoride to their products (Ref. 7). Therefore, we assume that between 1 percent and 3 percent of all manufacturers, or between 20 to 60 bottled water manufacturers, add fluoride to their products.

E. Benefits of the Final Rule

The final rule amends the allowable levels of fluoride in bottled water to which fluoride is added, making the standard for bottled water consistent with the updated PHS recommendations for the optimal fluoride concentration for community water systems that

fluoridate their water. The amendment is based on findings from evolving research on optimal concentrations of fluoride that would balance prevention of dental caries with the risk of dental fluorosis. Because of the importance of bottled water in per-capita water consumption, we assume consumers of fluoridated bottled water expect the same standard applies for added fluoride in bottled water as in community water systems. Consequently, making consistent the standards for added-fluoride between bottled water and community water systems may reduce potential consumer confusion about the level of fluoride in the water they consume, regardless of water source.

Based on the percentage of water bottlers that fluoridate their bottled water (between 1 percent and 3 percent), we expect the final rule will generate some benefit from continued prevention of dental caries while minimizing the risk of dental fluorosis. The final standard strives to achieve an optimal balance between the risks of dental caries and dental fluorosis.

We lack data on the quantity of bottled water to which fluoride is added (BWFA) consumed by children eight years and younger. The updated standard may reduce excess consumption of fluoride and the need for treatments related to effects from dental fluorosis. We assume there will be a small change in the risk of severe dental fluorosis.

Consumers may choose to seek cosmetic treatment, such as teeth whitening, for mild dental fluorosis. According to the on-line dentistry guide www.yourdentistryguide.com, the average in-office price of a teeth whitening procedure is $650 and prices for over-the-counter remedies are under $100 (Ref. 8). We assume there will be some change in risk of mild dental fluorosis from the final rule. We expect minimal to no change in dental caries as a result of the revised standard since most BWFA is already in compliance with the updated standard and therefore it is unlikely to increase the dental care costs for most consumers.

Finally, there may be some cost savings to bottled water manufacturers if they add less fluoride to BWFA. We do not quantify these savings because we do not know the current distribution of fluoride added to bottled water. We assume these savings are small since most manufacturers already comply with the new standard (Ref. 7).

F. Costs of the Final Rule

While labeling the amount of fluoride added to bottled water is outside the scope of this rule, we note that mandatory declaration of the amount of fluoride is required if a claim about fluoride content is made on the label or in the labeling. We are not aware of manufacturers currently including claims about fluoride content on labels of bottled water that would require fluoride content labeling. Consequently, we assume that manufacturers will continue this business practice, and thus, the final rule will not result in any labeling changes.

We assume that all bottled water manufacturers will incur one-time costs to read and understand the rule. This may overstate reading and understanding costs to the extent that manufacturers that do not add fluoride to their bottled water products will not read and understand the rule. In addition, we assume that only bottled water manufacturers that add fluoride to their finished product will incur one-time costs to verify the fluoride level after adjustment of the manufacturing process. We assume the costs to read and understand the rule and the costs to verify fluoride levels are the same for domestic and foreign manufacturers.

1. One-time costs to read and understand the rule

We estimate that a regulatory affairs expert will incur a burden of between 15 and 30 minutes to access the rule and would read the provisions at a rate of 200 to 250 words per minute

(Ref. 9). The preamble and codified regulation are approximately 7,390 words and we estimate that it will take between 0.4927 and 0.6158 hours for a legal affairs expert to read the final rule.

We estimate the mean hourly wage of a regulatory affairs expert using wages reported in the Bureau of Labor Statistics, *Occupation Employment Statistics*, May 2020 (Ref. 1) National Industry-Specific Occupational Employment Estimates for a Lawyer (Occupation Code 23-1011). Following HHS guidance, we double this wage to account for benefits and overhead to obtain a fully loaded wage of $143.18 (Ref. 9). Applying the fully loaded mean hourly wage to the hourly burdens described earlier we obtain a cost of between $106.34 and $159.76 for a regulatory affairs expert to access and read the rule (between 0.25 and 0.5 hours to access the rule + between 0.4927 hours and 0.6158 hours to read the rule x $143.18 per hour). We estimate the total cost to read and understand the rule to be between $213,637.06 and $320,957.84 (2,009 bottled water manufacturers incurring costs of between $106.34 and $159.76).

We assume that each manufacturer would incur the cost to read and understand the rule the first year following publication of the rule. Assuming a discount rate of 7 percent over 10 years, we estimate the annualized costs range from $30,417.11 to $45,697.18. Assuming a discount rate of 3 percent over 10 years, the annualized costs range from $25,044.78 to $37,626.05.

2. One-time costs to verify the fluoride level after adjustment of the manufacturing process

We assume that bottled water manufacturers that choose to add fluoride to their products will incur a one-time cost to verify the fluoride level after adjustment of the manufacturing process to ensure that such bottled water complies with the standards in this final rule. There may be some bottled water manufacturers that already meet the standard for added fluoride.

Communications with industry suggest that adding fluoride to bottled water is done by injecting or mixing a fluoride "brine" solution into the water during production (Ref. 10). We assume the costs for injecting or mixing fluoride into bottled water to the required concentration will remain unchanged. There may be some cost savings from lowerering the concentration of fluoride in BWFA.

We assume that each manufacturer that adds fluoride to their bottled water will conduct between one and two additional analytical tests, after adjustment of the manufacturing process, to verify the fluoride level and ensure that such bottled water complies with the required standards. We obtain the range in testing costs for finished bottled water from the economic analysis of the 2009 bottled water final rule (79 FR 25651 at 25658, May 29, 2009) and use those to estimate the testing costs for this final rule. We inflate the testing costs reported in the analysis of the 2009 bottled water final rule to 2020 dollars using the Consumer Price Index and obtain a range of between $36.66 and $103.17 per test.

We assume that between 1 percent and 3 percent of all water bottlers add fluoride to their products and will incur one-time costs from one to two additional tests to verify the fluoride level after adjustment of the manufacturing process. Consequently, we estimate a one-time cost of between $36.66 and $206.34 per firm (1 test @ $36.66 per test = $36.66, and 2 tests @ $103.17 per test = $206.34), and between $733.20 and $12,380.40 for all manufacturers of BWFA to verify the fluoride level after adjustment of the manufacturing process (20 bottled water manufacturers x $36.66 to verify fluoride the level = $733.20, and 60 bottled water manufacturers x $206.34 to verify the fluoride level =$12,380.40).

We assume that each manufacturer will incur the one-time verification costs the first year following publication of the rule. Assuming a discount rate of 7 percent over 10 years, we

estimate the annualized verification costs range from $104.39 to $1,762.69 with a primary estimate of $933.54. Assuming a discount rate of 3 percent over 10 years, the annualized verification costs range from $85.95 to $1,451.36 with a primary estimate of $768.66. We report the one-time costs and annualized costs in Table 2 and Tables 3a and 3b.

Table 2: One-time costs

	Lower bound	Primary estimate	Upper bound
Cost to read and understand the rule	$213,637.06	$267,297.45	$320,957.84
Cost to verify fluoride levels	$733.20	$6,556.80	$12,380.40
Total	**$214,370.26**	**$273,854.25**	**$333,338.24**

Table 3a: Annualized costs at 7 percent over 10 years

	Lower bound	Primary estimate	Upper bound
Cost to read and understand the rule	$30,417.11	$38,057.14	$45,697.18
Cost to verify fluoride levels	$104.39	$933.54	$1,762.69
Total	**$30,521.50**	**$38,990.68**	**$47,459.87**

Table 3b: Annualized costs at 3 percent over 10 years

	Lower bound	Primary estimate	Upper bound
Cost to read and understand the rule	$25,044.78	$31,335.42	$37,626.05
Cost to verify fluoride levels	$85.95	$768.66	$1,451.36
Total	**$25,130.73**	**$32,104.07**	**$39,077.41**

G. Distributional Effects

We assume there will be no distributional effects on consumers or bottled water manufacturers from the rule. We assume between one percent and three percent of bottled water manufacturers will be affected by the final rule. Manufacturers that do not add fluoride to their bottled water products will not be affected. We assume that all costs will be incurred by manufacturers and not be passed on to bottled water consumers.

H. International Effects

We assume there will be minimal to no effect on international trade from the rule. We estimate between 20 and 60 bottled water manufacturers add fluoride to their products, some of which may be international. Domestic and international bottled water manufacturers selling and marketing bottled water in the U.S. will incur the costs to read and understand the rule as well as costs to verify fluoride levels following adjustment to their manufacturing process. Domestic and international bottled water manufacturers that do not add fluoride to their products will not be affected.

I. Uncertainty and Sensitivity Analysis

The one-time costs to read and understand the rule range from about $213,637 to about $320,958. Most of the uncertainty in the costs to read and understand the rule comes from uncertainty in the burdens for bottled water manufacturers to access and read the rule. The costs to verify fluoride levels following adjustment range from about $733 to $12,380. Most of the uncertainty in the costs to verify fluoride levels is from uncertainty in the number of manufacturers of BWFA which we estimate to be between 20 and 60.

J. Analysis of Regulatory Alternatives to the Rule

We consider two regulatory alternatives to the final rule: (1) Change the standard for BWFA to the range 0.6 mg/l to 1.0 mg/L while maintaining all other aspects of the final rule, and (2) extending the compliance date to 18 months after the effective date of the final rule, while maintaining all other aspects of the final rule.

1. Change the standard to the range 0.6 mg/L to 1.0 mg/L for the fluoride concentration in bottled water to which fluoride is added.

This regulatory alternative is consistent with a recommendation made by one comment. It provides for a range of fluoride concentrations of between 0.6 mg/L and 1.0 mg/L, instead of the single maximum value (0.7 mg/L) in the final rule, and would be consistent with the CDC's proposed operational control range around the optimal fluoride concentration in community water systems that adjust fluoride (83 FR 32666). However, as stated in the preamble to the final rule, data indicates that most BWFA that is sold or offered for sale in the U.S. now has no more than 0.7 mg/L fluoride. To the extent that BWFA is currently calibrated to contain less than 0.6 mg/L, manufacturers would incur costs to add enough fluoride to their BWFA to reach the minimum of the range for this regulatory alternative (0.6 mg/L). Moreover, we have determined that the level of 0.7 mg/L to BWFA provides the greatest public health benefit. Consequently, we estimate the costs of this regulatory alternative could be greater than those for the final rule and the public health benefits from this regulatory alternative could be less than those for the final rule.

2. Delay the compliance date to 18 months after the date of publication

This regulatory alternative is consistent with a comment suggesting that inventories of BWFA that conform to the existing standard may exist after the effective date. The comment did not provide, and we are not aware of any information suggesting that there will be product remaining in inventories that does not comply with the rule after the compliance date. However, as stated in the preamble to the final rule, data indicates that most BWFA that is sold or offered for sale in the U.S. now has no more than 0.7 mg/L fluoride. Therefore, we do not expect any

significant amount of BWFA still in inventory to contain fluoride at levels above 0.7 mg/L. Consequently, delaying the effective date of compliance from 180 days to 18 months would have minimal impact on costs and benefits.

III. Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a rule will have a significant effect on a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities. This final rule revises the standard for the allowable concentration of fluoride in bottled water to which fluoride is added, to match the PHS recommended optimal concentration for community water system fluoridation. We do not expect the revision to the standard will significantly increase costs associated with manufacturing bottled water products, and thus certify that the rule will not significantly affect a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities. The discussion in this section and the previous sections of the economic analysis constitute the regulatory flexibility analysis.

A. Description and Number of Affected Small Entities

The Regulatory Flexibility Act requires a description of the small entities that will be affected by the rule, and an estimate of the number of small entities to which the rule will apply. The final rule will affect bottled water manufacturers. We apply the Small Business Administration (SBA) size standard for bottled water manufacturers to the size distribution of bottled water manufacturers reported in US Census data to estimate the number of manufacturers covered by this final rule that are small. According to the SBA Table of Small Business Size

Standards (Ref. 11), bottled water manufacturers are considered small if they have fewer than 1,001 employees.

We do not know the size distribution of the bottled water manufacturers reported in the FDA internal data sources that we used to estimate the number of entities that will be affected by the final rule. We assume the size distribution is the same as that reported in the 2013 County Business Patterns for bottled water manufacturers under the North American Industry Classification System (NAICS) code 312112 (Ref. 12). Table 4 shows the size distribution for bottled water manufacturers under NAICS code 312112 obtained from the 2013 County Business Patterns. According to the SBA Table of Small Business Size Standards (Ref. 11), bottled water manufacturers are considered small if they have fewer than 1,001 employees. According to the size distribution reported in Table 4, all bottled water establishments covered by the final rule have fewer than 1,001 employees and would be considered small by the SBA standards.

Table 4: The distribution of bottled water manufacturing establishments by number of employees[1]

Number of Employees	Number of Establishments	Percent of Total Establishments
1-4	109	37%
5-9	45	15%
10-19	35	12%
20-49	46	16%
50-99	38	13%
100-249	32	11%
250-499	4	1%
500-999	0	0%
1000 or more	0	0%

[1] Derived from US Census, 2013 County Business Patterns, NAICS 312112

B. Description of the Impacts of the Rule on Small Entities

From the Final Economic Analysis of Impacts we estimate the one-time costs for bottled water manufacturing firms to read and understand the rule and to verify the fluoride level after

adjustment of the manufacturing process range from $118.51 to $776.01 per firm. This estimate assumes that all bottled water manufacturers will incur one-time costs to read and understand the rule, and between 20 and 60 bottled water manufacturers add fluoride to their products and will incur one-time costs to verify fluoride levels.

Data from the US Census, 2013 County Business Patterns reports revenue from shipments of bottled water from 294 domestic bottled water manufacturers to be $5.739 billion for an average of approximately $19.5 million per bottled water manufacturing establishment (Ref. 12). We note that the total number of domestic bottled water manufacturing establishments reported in the 2013 County Business Patterns data (294) is less than the total number of domestic bottled water manufacturers estimated earlier using internal data (669). We explain this difference by noting the internal data's inclusion of seasonal and inactive bottler water manufacturing operations which are likely not included in the US Census data. The upper bound of the range in one-time cost estimates of the final rule represents approximately 0.004 percent of the average annual value of shipments for a small bottled water manufacturer. Because the clarifications in this final rule will not significantly increase costs on bottled water manufacturers, we certify that this rule will not have a significant economic impact on a substantial number of small entities.

IV. References

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