DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Docket No. FDA- FDA-2018-N-1815

Preliminary Regulatory Impact Analysis
Initial 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 proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This proposed rule is a significant regulatory action as defined by EO 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because updating the standards the allowable level for fluoride in bottled water to which fluoride has been added specified in this proposed rule would not significantly increase costs to bottled water manufacturers, we propose to certify that the proposed 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 proposing "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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule would revise the bottled water quality standard for the allowable level for fluoride to 0.7 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). 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 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.

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. The one-time costs range between $129,802.42 and $224,554.41. When discounted at seven percent over 10 years, the annualized costs range from $18,480.94 and $31,971.50. When discounted at three percent over 10 years the annualized costs range from $15,216.80 and $26,324.63. In Table 1, we provide the Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated Information System accounting information on the annualized costs and

benefits of the proposed 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%		
						3%		
	Qualitative	Update standard to make consistent with current PHS recommendations						
Costs	Annualized Monetized $millions/year	$0.025	$0.018	$0.032	2017	7%	10 years	
		$0.021	$0.015	$0.026	2017	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							

In Table 2 we show a summary of the costs, cost savings and net costs. This proposed rule, if finalized, is considered an EO 13771 regulatory action.

Table 2--EO 13771 Summary (in $ Millions 2016 dollars) over an infinite time horizon

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$0.177	$0.130	$0.225	$0.177	$0.130	$0.225
Present Value of Cost Savings	$0	$0	$0	$0	$0	$0
Present Value of Net Costs	$0.177	$0.130	$0.225	$0.177	$0.130	$0.225
Annualized Costs	$0.012	$0.009	$0.016	$0.005	$0.004	$0.007
Annualized Cost Savings	$0	$0	$0	$0	$0	$0
Annualized Net Costs	$0.012	$0.009	$0.016	$0.005	$0.004	$0.007

II. Preliminary Regulatory Impact Analysis

A. Background

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, PHS published a final recommendation notice that updated and replaced the 1962 Standards related to community water fluoridation (available at: https://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10201.pdf. The PHS now recommends the optimal fluoride concentration of 0.7 mg/L for community water systems. 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. 1). 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 proposed rule addresses an institutional failure. Without revising the appropriate standard bottled water manufacturers should follow when adding fluoride, some bottled water might have levels of added fluoride inconsistent with PHS recommendations for community water fluoridation. 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 (80 FR 24936, May 1, 2015). 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.

Our proposed rule would revise the allowable level for fluoride in bottled water to which fluoride is added, to align with the updated PHS recommendation, and this allowable level would apply equally to foreign and domestic bottled water manufacturers. 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. 2). Updating our bottled water quality standard to match the recommendation for community water systems that add fluoride would improve public health by ensuring consistency with these PHS recommendations. To the extent that bottled water manufacturers continue current practices based on the 1962 Drinking Water Standards, which have been replaced by updated recommendations, we have created an institutional failure by not updating our bottled water standards. The proposed rule would correct this institutional failure and would also reduce any confusion on the part of consumers that may exist regarding the fluoride added to bottled water.

C. Baseline Conditions

Number of entities affected by the rule

FDA internal data indicate that there are 669 domestic bottled water manufacturing establishments that have been subject to an inspection between 2002 and 2016, and would be affected by the proposed rule. These include establishments that are both inactive and seasonal as well as establishments that currently manufacture bottled water year-round. FDA internal data covering FY2015 and most of FY2016 indicate that we have imported bottled water from approximately 1,340 foreign manufacturing establishments. Consequently, we estimate that there would be 2,009 foreign and domestic bottled water establishments that would be affected by the proposed rule (699 + 1,340 = 2,009). Information from International Bottled Water Association (IBWA) suggests that no more than 3 percent of bottled water manufacturers add fluoride to their products (Ref. 3). 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.

D. Benefits of the Proposed Rule

The proposed rule, if finalized would amend the maximum 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 that consumers of fluoridated bottled water would 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. We request comment on this assumption.

Based on the percentage of water bottlers that fluoridate their bottled water (between 1 percent and 3 percent), we expect the proposed rule, if finalized, would generate some benefit from continued prevention of dental caries while avoiding the potential risk of unnecessary dental fluorosis. The proposed standard strives to achieve a balance that maximizes the benefits of fluoridated bottle water.

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. 4). 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.

We lack data on the quantity of bottled water to which fluoride is added consumed by children eight years and younger. However, we expect that bottled water to which fluoride is added accounts for a small amount of the total fluoride consumption by children in this age group. The proposed updated standard might reduce excess consumption of fluoride and the need for treatments related to effects from dental fluorosis. We assume there would be some change in the risk of severe dental fluorosis from the proposed rule and request comment on this assumption.

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. 5). We assume there would be some change in risk of mild dental fluorosis from the proposed rule and request comment on this assumption. The revised standard would continue to provide sufficient protection against dental caries and would be unlikely to increase the dental care costs for most consumers. The CDC reports that approximately 91 percent of US adults aged 20-64 had dental caries in permanent teeth in 2011-2012 (Ref. 6). We request any data to quantify the changes in the risk of severe or mild dental fluorosis from the proposed rule.

E. Costs of the Proposed Rule

There is no requirement that the fluoride content appear on labels of bottled water, except when a manufacturer makes a claim about fluoride content. 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 the proposed rule, if finalized, would not require labeling changes. We ask for comment on this assumption.

We assume that all bottled water manufacturers could incur one-time costs to learn the rule. This may overstate learning costs to the extent that the proposed rule may not apply to manufacturers that do not add fluoride to their bottled water products. We assume that only bottled water manufacturers that add fluoride to their finished product would incur one-time costs to verify the fluoride level after adjustment of the manufacturing process.

One-time costs to learn the rule

We model the one-time learning costs as the time required by manufacturers' regulatory affairs experts to access and read the proposed rule. We estimate that a regulatory affairs expert would 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. The preamble and codified regulation are

approximately 3,315 words and we estimate that it would take between 0.221 and 0.276 hours for a legal affairs expert to read the proposed 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, 2017 (Ref. 7) National Industry-Specific Occupational Employment Estimates for a Lawyer (Occupation Code 23-1011) which we double to account for overhead to obtain a fully loaded wage of $136.44. Applying the fully loaded mean hourly wage to the hourly burdens described earlier we obtain a cost of between $64.26 and $105.91 for a regulatory affairs expert to access and read the proposed rule (between 0.25 and 0.5 hours to access the rule + between 0.221 hours and 0.276 hours to read the rule x $136.44 per hour) and the total access and learning costs to be between $129,104.85 and $212,776.30 (2,009 bottled water manufacturers incurring access and learning costs of between $64.26 and $105.91).

We assume that each manufacturer would incur the access and learning costs the first year following publication of the rule. When we assume a discount rate of 7 percent over 10 years, we estimate the annualized access and learning costs range from $18,381.63 to $30,294.56. When we assume a discount rate of 3 percent over 10 years, the annualized access and learning costs range from $15,135.03 to $24,943.87.

<u>One-time costs to verify the fluoride level after adjustment of the manufacturing process</u>

We assume that bottled water manufacturers that choose to add fluoride to their products would 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 proposed rule. There may be some bottled water manaufacturers that already meet the proposed standard for added fluoride. We ask for comment on this possibiloity. Communications with the IBWA suggest that

adding fluoride to bottled water is done by injecting or mixing a fluoride "brine" solution into the water during production (Ref. 8). We assume the costs for injecting or mixing fluoride into bottled water to the proposed concentration would be remain unchanged.

We assume that each manufacturer that adds fluoride to their bottled water would incur between one and two additional tests, after adjustment of the manufacturing process, to verify the fluoride level and ensure that such bottled water complies with the standards in this proposed rule. 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 proposed rule. We inflate the testing costs reported in the analysis of that final rule to 2017 dollars and obtain a range of between $34.72 and $97.71 per test. We request comment on this estimate.

Using the information provided by the IBWA, we assume that between 1 percent and 3 percent of all water bottlers add fluoride to their products and would incur the 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 $34.72 and $195.42 per firm (1 test @ $34.72 per test = $34.72, and 2 tests @ $97.71 per test = $195.42), and between $697.57 and $11,778.11 for all bottled water manufacturers to verify the fluoride level after adjustment of the manufacturing process (1 percent x 2,009 bottled water manufacturers x $34.72 to verify fluoride the level = $697.57, and 3 percent x 2,009 bottled water manufacturers x $195.42 to verify the fluoride level = $11,778.11).

We assume that each manufacturer would incur the one-time verification costs the first year following publication of the rule. When we assume a discount rate of 7 percent over 10 years, we estimate the annualized verification costs range from $99.32 to $1,676.94. When we

assume a discount rate of 3 percent over 10 years, the annualized verification costs range from $81.78 to $1,380.75. We report the one-time costs and annualized costs in Table 3 and Tables 4a and 4b.

Table 3: One-time costs

	Lower bound	Medium estimate	Upper bound
Learning costs	$129,104.85	$170,940.58	$212,776.30
Verification costs	$697.57	$6,237.84	$11,778.11
Total	$129,802.42	$177,178.41	$224,554.41

Table 4a: Annualized costs at 7 percent over 10 years

	Lower bound	Medium estimate	Upper bound
Learning costs	$18,381.63	$24,338.09	$30,294.56
Verification costs	$99.32	$888.13	$1,676.94
Total	$18,480.94	$25,226.22	$31,971.50

Table 4b: Annualized costs at 3 percent over 10 years

	Lower bound	Medium estimate	Upper bound
Learning costs	$15,135.03	$20,039.45	$24,943.87
Verification costs	$81.78	$731.26	$1,380.75
Total	$15,216.80	$20,770.72	$26,324.63

IV. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a proposed rule would have a significant effect on a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities. This proposed rule, if finalized, would revise the standard for the maximum 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 would significantly increase costs associated with marketing bottled water products, and thus certify that the proposed rule would 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 would be affected by the rule, and an estimate of the number of small entities to which the rule would apply. The proposed rule would affect domestic 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 proposed rule that are small.

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 would be affected by the proposed rule. We assume that 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. 9). Table 1 shows the size distribution for bottled water manufacturers under NAICS code 312112 obtained from the 2013 County Business Patterns. According the SBA Table of Small Business Size Standards (Ref. 10), bottled water manufacturers are considered small if they have fewer than 1,001 employees. According to the size distribution reported in Table 1, all bottled water establishments covered by the proposed rule have fewer than 1,001 employees and would be considered small by the SBA standards.

Table 1: 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 Potential Impacts of the Rule on Small Entities

From the Preliminary Regulatory Impact Analysis we estimate the one-time costs for bottled water manufacturing firms to access and learn the rule and to verify the fluoride level after adjustment of the manufacturing process range from $75.84 to $692.18 per firm. This estimate assumes that all bottled water manufacturers would incur one-time costs to access and learn the rule, and 10 percent to 30 percent of bottled water manufacturers add fluoride to their products and would 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. 9). 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 (699). 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 proposed rule ($692.18 per firm) would represent approximately 0.004 percent of the average annual value of shipments for a small bottled water manufacturer. Because the clarifications in this proposed rule would not significantly increase costs on bottled water manufacturers, we propose to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

V. References

1. "Letter to Manufacturers, Distributors, or Importers of Bottled Water with an Update on Fluoride Added to Bottled Water," dated April 27, 2015, from Susan T. Mayne, Ph.D., F.A.C.E., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, accessed on the Internet at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/bottledwatercarbonatedsoftdrinks/ucm444373.htm).
2. 2013-2016 National Health and Nutrition Examination Surveys
3. IBWA Communication to H. Kim, FDA, Letter, 6/15/2018.
4. CDC, Community Water Fluoridation, Fluorosis, https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm, accessed 10/22/2018
5. Dyett, Linda, "In-Office Teeth Whitening: Professional Advantages, Costs and Options." www.yourdentistryguide.com/professional whitening/, accessed May 19, 2017.
6. Dye, Bruce A.; Gina Thornton-Evans; Xianfen Li; and Tim othy J. Iafolla, "Dental Caries and Tooth Loss in Adults in the United States, 2011-2012;" *NCHS Data Brief*, No. 197, May 2015, https://www.cdc.gov/nchs/data/databriefs/db197.pdf.
7. Department of Labor, Bureau of Labor Statistics, May 2017 National Occupational Employment and Wage Estimates United States, Occupation Code 23-1011, https://www.bls.gov/oes/current/oes_nat.htm#23-0000, accessed July 23, 2018.
8. FDA Memorandum, "Teleconference Related to Fluoride in Bottled Water," 2016.
9. US Census, 2013 County Business Patterns, http://thedataweb.rm.census.gov/TheDataWeb_HotReport2/econsnapshot/2012/snapshot.hrml?NAICS=312112, accessed July 27, 2016.

10. US Small Business Administration Table of Small Business Size Standards, https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf