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American Association for Dental Research

June 3, 2019

Dr. Yinqing Ma
Center for Food Safety and Applied Nutrition
Food and Drug Administration
c/o Dockets Management Staff
Rm. 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2018-N-1815 Beverages: Bottled Water

Dear Dr. Ma:

On behalf of the 3,350 individual and 107 institutional members of the American Association for Dental Research (AADR), thank you for the opportunity to provide input on the proposed rule, "Beverages: Bottled Water" (Docket No. FDA-2018-N-1815). Overall, AADR supports this proposed rule that fluoride added to both domestic and imported bottled water should not exceed 0.7 milligrams fluoride per liter water (mg/L) in accordance with the latest recommendation for community water systems by the U.S. Public Health Service (PHS). This level is intended to maximize prevention of tooth decay while reducing the risk of severe dental fluorosis.

The proposed rule acknowledges that "community water fluoridation is the most cost-effective method for delivering fluoride for the prevention of tooth decay". Community water fluoridation delivers fluoride on a population level such that if the community decides to fluoridate its water, consumers will benefit regardless of income or access to dental services. A recent study showed that community water fluoridation may reduce dental caries in primary teeth related to income inequality.[1] In 2018, the AADR Council passed a policy statement supporting community water fluoridation because it is safe, effective and reduces dental care costs.[2] The proposed rule states that bottled water is increasingly replacing tap water as a drinking water source. Therefore, it is important that those who primarily consume bottled water have the same access to tooth decay prevention through fluoride as those who consume tap water.

As the proposed rule states, many bottled water manufacturers have already adjusted how much fluoride is in their water due to an earlier notification by FDA of its intent to update this rule in compliance with the recommendation from PHS. This proposed rule will create one simple, easy-to-follow and easy to understand standard for both

[1] Sanders AE, Grider WB, Maas WR, Curiel JA, Slade GD. 2019. Association Between Water Fluoridation and Income-Related Dental Caries of US Children and Adolescents. *JAMA Pediatr.* 173(3):288–290.
[2] AADR Policy Statement on Community Water Fluoridation. [accessed 29 May 2019]. https://www.iadr.org/AADR/About-Us/Policy-Statements/Science-Policy/Community-Water-Fluoridation.

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manufacturers and consumers and bring remaining manufacturers who have yet to change fluoridation practices in line with the new recommendation.

AADR supports removing references to daily air temperatures from the current rule, which dictates that the allowable fluoride level in bottled water is determined by the maximum daily air temperatures at the location where the bottled water is sold. The U.S. PHS determined temperature to be irrelevant to the expected amount of water consumption and, therefore, fluoride exposure from drinking water.

The optimal level of 0.7 mg/L recommended by the U.S. PHS is intended to maximize caries prevention and minimize the risk of severe dental fluorosis. However, it has come to light recently that the fluorosis data collected by the Centers for Disease Control and Prevention (CDC) through the National Health and Nutrition Examination Survey is likely unreliable due to examiner subjectivity in diagnosing fluorosis as determined by a data quality assessment released on April 22, 2019.[3] AADR has advocated for these new data to be catalysts for research on objective methods for diagnosing fluorosis.[4] AADR encourages FDA to monitor developments in fluorosis research and surveillance and to proactively work with other entities in the Department of Health and Human Services like PHS and CDC to update this rule as more data become available.

Finally, while AADR largely supports the provisions of the proposed rule, it requests more information about the FDA's rationale for restricting the rule to bottled water to which fluoride is added and not expanding the rule to water bottled from a source with naturally-occurring fluoride. Having different standards for these types of bottled water will be confusing to consumers. Furthermore, the quality standard for domestically bottled water from a naturally-fluoridated source is still based on the ambient temperature of the retail location, which both the PHS and FDA – through this proposed rule – have said are not associated with total water consumption and fluoride exposure. AADR encourages FDA to create one standard for all bottled water – regardless of whether fluoride is added or not – or to provide a thorough rationale for this exception.

To summarize, AADR supports updating the standard for fluoride added to both domestic and imported bottled water to 0.7 mg/L in line with the recommendation from the PHS. AADR encourages FDA to either expand this proposed rule to water bottled from sources with naturally-occurring fluoride or to provide a rationale for this exclusion.

Once again, AADR is grateful for the opportunity to submit comments on this proposed rule, and we stand ready to work with FDA as the rule is finalized. Please do not hesitate to reach out to Dr. Seun Ajiboye, Director of Science Policy and Government Affairs, at sajiboye@iadr.org if you need any other information.

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[3] National Center for Health Statistics, National Center for Chronic Disease Prevention and Health Promotion. 2019. Data quality evaluation of the dental fluorosis clinical assessment data from the National Health and Nutrition Examination Survey, 1999–2004 and 2011–2016. National Center for Health Statistics. *Vital Health Stat* 2(183).

[4] AADR Response to New NCHS Evaluation of Dental Fluorosis Clinical Assessment Data from NHANES Over Time. [accessed 29 May 2019]. http://ga.dentalresearchblog.org/?p=3344.

Sincerely,

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