



Memorandum to the File

Date: July 28, 2016

From: Henry Kim, Senior Policy Analyst, FDA CFSAN/OFS

Re: Teleconference related to fluoride in bottled water

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I contacted Robert Hirst of International Bottled Water Association (IBWA) via phone to get a better understanding of bottled water industry practices on addition of fluoride to bottled water products.

Mr. Hirst informed me that fluoride is added to bottled water by first preparing or purchasing fluoride "brine" solution at a certain fluoride concentration that is automatically injected to bottled water during production. This is considered automated system for adding fluoride by most bottled water manufacturers. When concentration of fluoride needs to be changed in finished bottled water product, the fluoride concentration in the "brine" solution is adjusted.

I mentioned that in response to the updated U.S. Public Health Service (PHS) recommendation of an optimal fluoride concentration of 0.7 mg/L for community water systems that are currently fluoridating or will initiate fluoridation of their water to maintain dental caries prevention benefits and reduce the risk of dental fluorosis, FDA intends to revise the quality standard for fluoride added to bottled in 21 CFR 165.110(b)(4)(ii) to be consistent with the updated PHS recommendation. Mr. Hirst stated that most IBWA member companies have already adjusted fluoride addition to obtain the 0.7 mg/L fluoride in their finished bottled water products in response to updated PHS recommendation and FDA's intention to revise the quality standard for fluoride added to bottled water to be consistent with the updated PHS recommendation.

A handwritten signature in black ink that reads "Henry Kim".

Henry Kim