FDA Proposes Rule to Prohibit Brominated Vegetable Oil in Food

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- In a *Federal Register* notice scheduled to be published November 3, the U.S. Food and Drug Administration (FDA) is proposing to revoke the regulation authorizing the use of brominated vegetable oil (BVO) in food (21 CFR § 180.30). BVO is a vegetable oil that is modified with bromine. As currently authorized, it is used in small amounts to keep citrus flavoring from floating to the top of some beverages. BVO was removed from the codified list of Generally Recognized as Safe (GRAS) substances in 1970.
- The Agency concluded that the intended use of BVO in food is no longer considered safe after the results of studies conducted in collaboration with the National Institutes of Health (NIH) found the potential for adverse health effects in humans. Results from these studies show bioaccumulation of bromine and toxic effects on the thyroid a gland that produces hormones that play a key role in regulating blood pressure, body temperature, heart rate, metabolism and the reaction of the body to other hormones.
- This proposal comes soon after California <u>passed AB 418</u> in October, which prohibits BVO and other chemicals in food manufactured, sold, delivered, distributed, held, or offered in the state beginning in 2027. However, FDA's proposed revocation of BVO was already listed on the Spring 2023 Regulatory <u>Agenda</u>.
- Comments regarding the proposed rule must be submitted by January 17, 2024. Keller and Heckman will continue to monitor the rulemaking process and will relay any developments.

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