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FDA is Asked to Approve Vitamin D3 For Use as a Nutrient Supplement in Grain-Based Nutrition Bars and at Higher Levels Than Currently Affirmed as GRAS in Breakfast Cereals

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- As a vitamin that is assigned a Reference Daily Intake (RDI) in 21 C.F.R. § 101.9(c)(8)(iv), vitamin D is an "essential nutrient." Vitamin D without a subscript represents either vitamin D_2 or vitamin D_3, which are the two major physiologically relevant forms of vitamin D. Vitamin D is affirmed as generally recognized as safe (GRAS) for use as a nutrient supplement in certain foods at the specified maximum levels in 21 C.F.R. § 184.90. The Food and Drug Administration (FDA) permits the fortification of some other types of foods with vitamin D under 21 C.F.R. § 172.380 ("Vitamin D_3").

- On August 12, 2019, FDA announced the filing of a food additive petition (FAP 9A4823) submitted by Kellogg Company to amend Section 172.380 to provide for the safe use of vitamin D_3 as a nutrient supplement in breakfast cereals and grain-based nutrition bars (*e.g.,* granola bars). While no additional information is available in the relevant Docket No. FDA-2019-F-3519, the FAP presumably requests fortification of breakfast cereals with vitamin D_3 at a level greater

than 350 International Units (IU) per 100 grams as is currently permitted under the GRAS regulation for vitamin D. There is no current GRAS regulation or food additive clearance for the use of vitamin D as a nutrient supplement in nutrient bars. Unlike breakfast cereals, nutrient bars are not among the categories of food that are defined in 21 C.F.R. § 170.3(n), but nutrient bars has been identified as a category for the purpose of determining intake of food ingredients in several GRAS notices.

- FDA may approve the use of a food additive only after conducting a scientific review to ensure safety by comparing the estimated daily intake (EDI) of the additive from the proposed use and all food sources to an acceptable intake level established by toxicological data. In a 2014 amendment of Section 172.380 to permit the use of vitamin D_3 as a nutrient supplement in certain meal replacement beverages, FDA adopted the upper limits (ULs) for vitamin D established for various age groups by the Institute of Medicine (IOM) as the highest average daily intake levels that poses no risk of adverse effects when consumed over long periods of time. We expect that FDA will apply the same framework for reviewing Kellogg's petition and, therefore, barring any new toxicological data, the proposed new use of vitamin D_3 in breakfast cereals and nutrition bars must not cause the EDI for vitamin D to exceed the relevant levels for various age groups in the range of IOM ULs for vitamin D for the U.S. population 1 year of age and older of 2,500 IU/person/day to 4,000 IU/person/day.

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