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FDA Warning Letter Takes Issue with Designation of Substance as Dietary Ingredient

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- In a Warning Letter posted yesterday (but issued in April), FDA warned Gluten Free Remedies LLC that one of their dietary supplement products was adulterated because it declared sulbutiamine as a dietary ingredient.
- Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 321 (ff)) defines a dietary supplement in part as a product (other than tobacco) intended to supplement the diet that bears of contains one or more of the following dietary ingredients: A) a vitamin; B) a mineral; C) an herb or other botanical; D) an amino acid; E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in A – E.
- Sulbutiamine is a synthetic derivative of thiamine (vitamin B_1) and so does not fit in the A – D dietary ingredient categories. In its New Dietary Ingredient Notifications and Related Issues draft guidance, FDA addresses the circumstances under which it would consider a synthetically produced substance to be a dietary ingredient, including in the context of substances in dietary ingredient category E (*see* pp. 37-38). FDA takes the position that a substance fitting the category E dietary ingredient criteria must be part of the human diet, and in the context of synthetic substances, requires the synthetic copy to have been lawfully marketed in the conventional food supply. Vanillin and cinnamic acid are offered as examples of such synthetic dietary ingredients.
- FDA has previously objected to the use of other substances that it has concluded do not meet the dietary ingredient definition. For example, it has taken the position that methylsynephrine, a synthetic stimulant, does not meet the dietary ingredient definition. *See e.g.*, Methylsynephrine in Dietary Supplements | FDA.
- The terms in dietary ingredient category E are not defined in the FD&C Act (FDA's interpretation in the draft guidance draws from dictionary definitions) and may be more susceptible to challenge since the Supreme Court overturned Chevron deference to agency decisions in *Loper Bright Enterprises v. Raimondo.*

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