



MAR 16 2020

Mr. Samuel A. Gonzalez

(b) (6)

Re: Docket Number FDA-2019-P-4448

Dear Mr. Gonzalez:

This letter is in response to your citizen petition received on September 24, 2019, in which you requested that the Food and Drug Administration (FDA, or we) amend 21 CFR 101.36(b)(ii)(2). Specifically, you requested that FDA add the sentence shown in bold font below to paragraph 21 CFR 101.36(b)(ii)(2).

“Protein shall not be declared on labels of products that, other than ingredients added solely for technical reasons, contains only individual amino acids. For the purposes of calories calculations, however, individual amino acids shall be given the same Atwater factor (4 calories per gram) as Protein.”

In accordance with Title 21 of the *Code of Federal Regulations*, section CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other agency priorities and the limited availability of resources. When we complete our review of your petition, we will notify you of our decision.

Please let us know if you have any questions.

Sincerely,

Claudine Kavanaugh, PhD, MPH, RD
Director
Office of Nutrition
and Food Labeling
Center for Food Safety
and Applied Nutrition

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cc:

HFS-800 (C. Kavanaugh, P. Hansen, D Benjamin)

HFS-830 (B. Fitzpatrick, J. Kevala)

HFS-024 K. Strambler

Drafted: HFS-830: JKevala: 03/13/2020

Edits: HFS:800: DRoe: 03/16/2020

NPS Cleared: HFS - 830: B Fitzpatrick 03/16/20