

CRN response to citizen petition filed on September 20, 2021 by Emery Pharma requesting FDA to require warning and restrict dosage of vitamin B6 dietary supplements:

Vitamin B6 is an essential nutrient that plays a role in numerous functions in the body and can be safely consumed from foods and dietary supplements. The petitioner's requests for FDA to require a warning statement on vitamin B6 or B-complex product labeling and to limit products containing more than 10 mg of vitamin B6 to be available by prescription only, are not supported by credible scientific evidence. In addition to lacking the scientific data that would be necessary for these policy changes, the requests would be harmful to consumers and deny them access to a range of beneficial products.

The citizen petition largely ignores the safe level of 100 mg/day for vitamin B6 intake set by U.S. authorities and does not include adequate information to warrant a change in this level. CRN's own safety review, last conducted in 2014, is consistent with government recommendations that vitamin B6 is safe at levels up to 100 mg/day.¹ The petitioner's requested actions would unnecessarily raise alarm and restrict access to an essential nutrient that is safely consumed by millions of Americans every day. As with other dietary supplements, it is prudent for individuals to talk to their healthcare provider about appropriate vitamin B6 intakes to support their health.

Additional information:

The National Academy of Medicine* established a tolerable upper intake level for vitamin B6 of 100 mg/day in adults, with careful consideration of evidence including data indicating that the risk of sensory neuropathy increases at intakes of 500 mg/day or higher.

*Formerly known as the Institute of Medicine

¹ JN Hathcock. Vitamin and Mineral Safety 3rd edition, 2014. Available at:
<https://www.crnusa.org/sites/default/files/files/resources/CRN-SafetyBook-3rdEdition-2014-fullbook.pdf>