



Memorandum

Date	June 24, 2019
From	[REDACTED], Ph.D. Toxicology Reviewer (HFS-255) Division of Food Ingredients (DFI) Office of Food Additive Safety (OFAS) Center for Food Safety and Applied Nutrition (CFSAN) Through [REDACTED] (HFS-255) Toxicology Branch Chief, HFS-255 [REDACTED]
Subject	Updated literature search and GRAS evaluation on picamilon (N-nicotinoyl- γ -aminobutyric acid)
To	[REDACTED], h.D. [REDACTED] Division Director, DFI, HFS-255

Keywords: picamilon/pikamilon/pycamilon/N-nicotinoyl- γ -aminobutyric acid/nicotinoyl-GABA/4-(Pyridine-3-carbonylamino) butanoic acid

This is an addendum to the November 16, 2015 memorandum that discussed the regulatory status and review of available information pertaining to picamilon. That memorandum concluded that “For the use of picamilon as an ingredient in food, FDA considers that the available scientific information ... raise safety concerns about the use of the substance ... there is no basis to conclude that the use of picamilon as an ingredient in conventional food is generally recognized as safe (GRAS).” This addendum summarizes the findings of an updated search of publicly available information since the original review.

The following database searches were performed on June 17, 2019:

- U.S. National Library of Medicine/Toxicology Data Network (TOXNET) using search terms “picamilon” OR “N-nicotinoyl-gamma-aminobutyric acid” OR “nicotinoyl-GABA”
- The National Center for Biotechnology/PubMed using search terms “picamilon” OR “N-nicotinoyl-gamma-aminobutyric acid” OR “nicotinoyl-GABA”
- Google using search terms “picamilon” OR “N-nicotinoyl-gamma-aminobutyric acid” OR “nicotinoyl-GABA”

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Based on these searches, only one new publication was found, which described the development of a validated analytical method for quantitation of picamilon in dietary supplements (Avula et al., 2016), information that does not impact the safety assessment.

Based on the updated literature search, no new information was identified that would change the conclusion as stated in our memorandum dated November 16, 2015.



Reference:

Avula, B., Chittiboyina, A.G., Sagi, S., Wang, Y.H., Wang, M., Khan, I.A., and Cohen, P.A. (2016). Identification and quantification of vinpocetine and picamilon in dietary supplements sold in the United States. *Drug Test Anal* 8, 334-343.