

ICF International, LLC 11/30/15



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

NOV 30, 2015

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Brandon Sojka
ICF International, LLC
840 Glynn Street South, Suite 338
Fayetteville, GA 30214

Re: 483228

Dear Mr. Sojka:

This letter concerns your product Myokem Nitramine, which is labeled and/or offered for sale as a dietary supplement. Your product labeling lists the substance Picamilon as a dietary ingredient. This ingredient is also called, among other names, pikatropin, pikamilon, nicotinyl-gamma-aminobutyric acid, and nicotinoyl-GABA (hereinafter referred to as picamilon).

Under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Picamilon is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In

addition, according to our research, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Finally, picamilon is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Rather, picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. As such, it is absorbed into the body, crosses the blood-brain barrier and accumulates in the brain as a separate chemical entity. Because picamilon does not fit any of the dietary ingredient categories under section 201(ff)(1) of the Act, it is not a dietary ingredient as defined in the Act. Declaring picamilon in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.

We request that you take prompt action to correct the violation cited above, as well as any other violations associated with your Myokem Nitramine product or other products marketed by your firm that list picamilon as a dietary ingredient in the labeling. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Failure to immediately cease distribution of your Myokem Nitramine product, and any other products you market that list picamilon as a dietary ingredient in the labeling, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Additionally, picamilon is not approved as a food additive or prior sanctioned for use in dietary supplements. Further, FDA's review of this substance does not identify a basis to conclude the substance is GRAS for use in food. If you contend that this substance is GRAS for use in food, please provide your basis for concluding that picamilon is GRAS for use in dietary supplements, including supporting data or other documentation.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to ensure that similar violations do not recur, as well as documentation to support your response. Your written reply should be directed to Aaron Dotson, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Aaron Dotson at [**aaron.dotson@fda.hss.gov \(mailto:aaron.dotson@fda.hss.gov\)**](mailto:aaron.dotson@fda.hss.gov).

Sincerely,

/S/

William A. Correll

Director

Office of Compliance

Center for Food Safety

and Applied Nutrition

More in 2015

(/ICECI/EnforcementActions/WarningLetters/2015/default.htm)