

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# Picamilon in Dietary Supplements

Picamilon is a substance that does not meet the statutory definition of a dietary ingredient.

The Federal Food, Drug, and Cosmetic Act (the Act) defines a dietary ingredient as 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. In contrast, picamilon is a unique chemical entity synthesized from the dietary ingredients niacin and gamma-aminobutyric acid. Picamilon 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 categories of dietary ingredients under the Act, any products marketed as dietary supplements that declare picamilon as a dietary ingredient are misbranded.

The FDA has provided expert testimony to the Oregon Attorney General's office stating that picamilon is not a dietary ingredient.

Picamilon is used as a prescription drug in Russia for a variety of neurological conditions. It is not approved as a drug in the U.S.

Picamilon is also known as:

- pikatropin
- pikamilon
- nicotiny-gamma-aminobutyric acid
- nicotiny-GAB

## Recent FDA Action on Dietary Supplements Labeled as Containing Picamilon

December 2015

On November 30, 2015, the FDA issued warning letters to five companies whose products marketed as dietary supplements claim to contain picamilon. These products are misbranded because picamilon does not meet the statutory definition of a dietary ingredient.

Under existing law, including the Dietary Supplement Health and Education Act passed by Congress in 1994, the FDA can take action to remove products from the market, but the agency must first establish that such products are adulterated (e.g., that the product is unsafe) or misbranded (e.g., that the labeling is false or misleading).

The companies have 15 business days from the date of receipt of the letter to communicate to the agency the specific steps they will take to bring their products into compliance with the law.

The agency will continue to update this page in the event additional actions are taken related to picamilon.

### Warning Letters

- **[DBM Nutrition for DBM Endurance World Championship Countess](/ICECI/EnforcementActions/WarningLetters/2015/ucm474808.htm)**  
**[\(/ICECI/EnforcementActions/WarningLetters/2015/ucm474808.htm\)](/ICECI/EnforcementActions/WarningLetters/2015/ucm474808.htm)**
- **[ICF International for Myokem Nitramine](/ICECI/EnforcementActions/WarningLetters/2015/ucm474788.htm)**  
**[\(/ICECI/EnforcementActions/WarningLetters/2015/ucm474788.htm\)](/ICECI/EnforcementActions/WarningLetters/2015/ucm474788.htm)**
- **[Top Secret Nutrition, LLC for Pump Igniter](/ICECI/EnforcementActions/WarningLetters/2015/ucm474833.htm)**  
**[\(/ICECI/EnforcementActions/WarningLetters/2015/ucm474833.htm\)](/ICECI/EnforcementActions/WarningLetters/2015/ucm474833.htm)**
- **[Applied Nutraceuticals, Inc. for HG4UP](/ICECI/EnforcementActions/WarningLetters/2015/ucm474816.htm)**  
**[\(/ICECI/EnforcementActions/WarningLetters/2015/ucm474816.htm\)](/ICECI/EnforcementActions/WarningLetters/2015/ucm474816.htm)**
- **[SDC Nutrition, Inc for NVIE Edge Pro](/ICECI/EnforcementActions/WarningLetters/2015/ucm474823.htm)**  
**[\(/ICECI/EnforcementActions/WarningLetters/2015/ucm474823.htm\)](/ICECI/EnforcementActions/WarningLetters/2015/ucm474823.htm)**

### More in **[Q & A on Dietary Supplements](/Food/DietarySupplements/QADietarySupplements/default.htm)**

**[\(/Food/DietarySupplements/QADietarySupplements/default.htm\)](/Food/DietarySupplements/QADietarySupplements/default.htm)**

**[BMPEA in Dietary Supplements](/Food/DietarySupplements/QADietarySupplements/ucm443790.htm)** **[\(/Food/DietarySupplements/QADietarySupplements/ucm443790.htm\)](/Food/DietarySupplements/QADietarySupplements/ucm443790.htm)**

**[DMAA in Dietary Supplements](/Food/DietarySupplements/QADietarySupplements/ucm346576.htm)** **[\(/Food/DietarySupplements/QADietarySupplements/ucm346576.htm\)](/Food/DietarySupplements/QADietarySupplements/ucm346576.htm)**

**[DMBA in Dietary Supplements](/Food/DietarySupplements/QADietarySupplements/ucm444719.htm)** **[\(/Food/DietarySupplements/QADietarySupplements/ucm444719.htm\)](/Food/DietarySupplements/QADietarySupplements/ucm444719.htm)**

▶ **[Picamilon in Dietary Supplements](/Food/DietarySupplements/QADietarySupplements/ucm472881.htm)** **[\(/Food/DietarySupplements/QADietarySupplements/ucm472881.htm\)](/Food/DietarySupplements/QADietarySupplements/ucm472881.htm)**

**[Pure Powdered Caffeine](/Food/DietarySupplements/QADietarySupplements/ucm460095.htm)** **[\(/Food/DietarySupplements/QADietarySupplements/ucm460095.htm\)](/Food/DietarySupplements/QADietarySupplements/ucm460095.htm)**