



**DECLARATION OF DR. CARA WELCH**

I, Dr. Cara Welch, declare as follows:

1. I am the Acting Deputy Director, Division of Dietary Supplement Programs (DDSP), Center for Food Safety and Applied Nutrition (CFSAN), United States Food and Drug Administration (FDA). In this capacity, I am responsible for the interpretation and application of relevant dietary supplement statute and regulations for the FDA's dietary supplement program office. This includes policies and programs involving regulatory compliance matters of significant importance to the dietary supplement industry regarding manufacturing and ingredient safety issues. The statements made in this declaration are based upon my personal knowledge and information about which I have become knowledgeable through my review of dietary supplement and ingredient issues.

2. Picamilon (pikatriptan) is a neurotransmitter (gamma-aminobutyric acid, GABA) that has been synthetically modified in order to facilitate its translocation across the blood-brain barrier. Picamilon is formed by synthetically combining niacin with GABA. There is no indication in the literature that this compound is found in nature.

3. A "dietary ingredient" under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) is "(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." 21 U.S.C. § 321(ff)(1).

4. Picamilon is not a vitamin. While picamilon may be synthesized from a vitamin (niacin), it is a different chemical entity. Picamilon is neither an organic substance nor a minor component of foods. Neither is picamilon essential for normal physiological functions. Picamilon is not produced endogenously in amounts adequate to meet normal physiologic needs

(and in fact, there is no physiologic need for picamilon), and there is no clinically defined deficiency syndrome associated with the absence or underutilization of picamilon. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(A) of the Act. 21 U.S.C. § 321(ff)(1)(A).

5. Picamilon is not a mineral as it does not provide a form or source of inorganic elements to the diet. Thus, picamilon does not does not qualify as a dietary ingredient under section 201(ff)(1)(B) of the Act. 21 U.S.C. § 321(ff)(1)(B).

6. Picamilon is not an herb or other botanical as it is not found in nature and is not a plant, alga, or fungus, nor an exudate thereof. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(C) of the Act. 21 U.S.C. § 321(ff)(1)(C).

7. Picamilon is not an amino acid. While picamilon contains an amino moiety along with a carboxylic acid, picamilon is a gamma-amino carboxylic acid, not an alpha-amino carboxylic acid. Additionally, picamilon is not a constituent of proteins. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(D) of the Act. 21 U.S.C. § 321(ff)(1)(D).

8. Picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. At my request, a diligent search of several food databases and scientific literature databases was conducted in August 2015 to identify food usage of picamilon. The search identified no food use of picamilon. In the absence of such a use, picamilon is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Thus, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(E) of the Act. 21 U.S.C. § 321(ff)(1)(E).

9. Picamilon is not a concentrate, metabolite, constituent, extract, or combination of any ingredient described in section 201(ff)(1)(A), (B), (C), (D), or (E) of the Act. 21 U.S.C. § 321(ff)(1)(A), (B), (C), (D), or (E). While picamilon is a synthetically modified version of niacin and GABA, both dietary ingredients on their own, it is a different chemical entity. Picamilon is absorbed into the body and even crosses the blood-brain barrier and accumulates in

the brain as this separate chemical entity. If picamilon dissociates into GABA and niacin, it would be a precursor to, not a metabolite of, dietary ingredients. Therefore, picamilon does not qualify as a dietary ingredient under section 201(ff)(1)(F) of the Act. 21 U.S.C. § 321(ff)(1)(F).

10. Because picamilon does not fit any of the dietary ingredient categories in section 201(ff)(1)(A)-(F) of the Act [21 U.S.C. § 321(ff)(1)(A)-(F)], it is not a dietary ingredient as set forth in section 201(ff)(1) of the Act. 21 U.S.C. § 321(ff)(1).

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

Executed on September 28, 2015

Cara Welch, Ph.D.  
Acting Deputy Director  
Division of Dietary Supplement Programs  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration



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Sworn to and subscribed  
before me this 28 day  
of September, 2015.

  
Notary Public

My commission expires:  
**ANA C. REYNOLDS**  
**NOTARY PUBLIC STATE OF MARYLAND**  
My Commission Expires January 16, 2018