In early December the FDA sent warning letters to five supplement companies, advising them that an ingredient they included in some of their products does not meet the standard for dietary ingredients. That substance is picamilon, which, the FDA states, is used as a prescription drug in Russia, but is not approved as a drug in the United States.

The FDA posted this definition of a dietary ingredient on its website:

"... 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."

But picamilon is a unique chemical entity that is produced in the laboratory from two other compounds GABA, or gamma-amino butyric acid, and nicotinic acid (a form of the B vitamin niacin).

It has been argued that because these two compounds occur naturally, their combined product should also be approved for inclusion in dietary supplements. However, that is a specious argument, because combining two chemical compounds could produce a third compound with very different effects. For example, the sweetener aspartame is composed of the amino acids phenylalanine and aspartic acid both naturally occurring in the human body. Neither of these is sweet but the combination is.

GABA is not able to cross the blood-brain barrier (BBB), while nicotinic acid is able to do so. But picamilon does cross the BBB, and once it is in the brain it breaks down to GABA and nicotinic acid. Supposedly this results in an increased level of GABA in the brain, and since it inhibits the activity of some neurons, it has been used (as a drug in Russia) as a sedative type of drug. But this does not make it a so-called "natural" product.

If picamilon is really effective for such uses, companies that want to use it in their products should go the route that all new drugs must follow for FDA approval. That is, demonstrating that the compound is both safe and effective for human use. Of course supplement companies don't want to do that, since it is an expensive and lengthy course to follow.
One thing is for sure these companies will most likely challenge the FDA's ruling. We will keep tabs on future actions in this area.

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