



February 8, 2023

VIA EMAIL:

Michael McGuffin

President, AHPA

E: mmcguffin@ahpa.org

Dear Mr. McGuffin:

Thank you for your December 23, 2022, inquiry regarding *Pinellia ternata* as a source of ephedrine.

As to the specific warning letter you referenced, it would not be appropriate to discuss details of this compliance action with a third-party.

As a general matter, FDA agrees that the determination of a dietary supplement as adulterated under 21 CFR 119.1 should be based on the product containing ephedrine alkaloids. In the absence of clear evidence that a product contains ephedrine alkaloids, FDA agrees that such a product would not be adulterated under 21 CFR 119.1.

Your inquiry also discusses three scientific publications looking at whether *P. ternata* contains ephedrine alkaloids. Based on our current review, it is our opinion that the publications confirming both the presence and, in another case, the absence of ephedrine alkaloids in *P. ternata* were not to the level of scientific rigor typically expected to definitively conclude that a particular substance is a constituent of a botanical. If you would like to discuss this further, we can make our scientists available for discussion.

Thank you, again, for your attention to this matter.

Sincerely,

Cara Welch, Ph.D.

Director

Office of Dietary Supplement Programs

Center for Food Safety and Applied Nutrition

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