SHEHADEH GIANNAMORE, PLLC

October 13, 2020

Sent via Electronic Mail
Mr. Esteban Fernández A.
Socio Fundador y CEO
Agrícola Los Esteros ltda

Re: FDA Dietary Ingredient Status for Dietary Supplement Products

Dear Mr. Garcia:

On behalf of Shehadeh Giannamore, PLLC, undersigned counsel would like to inform you that we have completed the review of the ingredient *Leptocarpha rivularis*, commonly referred to as Palo Negro. In conducting this review, we have determined that this ingredient may be permitted for use in dietary supplements due to its history in food use and to the extent it is not chemically altered.

Legal Background

On October 25, 1994, the Dietary Supplement Health and Education Act ("DSHEA") was signed into law, thereby amending the Federal Food, Drug and Cosmetic Act ("FDCA"). DSHEA amended the FDCA by, among other things, defining the term "new dietary ingredient" ("NDI").[1] In particular, "new dietary ingredient" is defined as "a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994."[2]

In addition to providing for grandfathered ingredients, DSHEA amended the FDCA by requiring the submission of a NDI premarket notification ("NDIN") at least 75 days prior to introducing the supplement into interstate commerce, where the ingredient used in considered a "new dietary ingredient", i.e., an ingredient that is not considered a grandfathered ingredient. Further, this law provides that a dietary supplement will be deemed adulterated where the supplement contains "a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. . . ."[3] Accordingly,

Under the FDCA (as amended by DSHEA) a NDIN is not always required where an ingredient is not considered grandfathered. In particular, a dietary supplement cannot be deemed adulterated under federal law where "[t]he dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food

[1] 21 USC § 350b.
[2] 21 USC § 350b(d).
[3] 21 USC § 342(f)(1)(B).

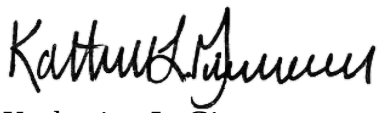
in a form in which the food has not been chemically altered."[4] This provision has been explained by the FDA to include ingredients used in conventional foods that have been marketed both in the United States and abroad. Accordingly, even where a NDIN has not previously been used in dietary supplements prior to October 15, 1994, it may be legally used in a supplement where the ingredient has been utilized in conventional foods. In sum, where dietary supplements contain only ingredients that have been marketed in conventional foods, including those marketed outside the U.S., these ingredients are ". . . exempt from the NDI notification requirement."[5]

Status of *Leptocarpha rivularis*

Based on a review of the ingredient *Leptocarpha rivularis*, commonly known as Palo Negro, we have determined that no NDIN is likely required under federal law for use in a dietary supplement, including tea products, because this ingredient has a history of food use as a whole leaf or plant extract in teas. To the extent that the extract ingredient is not "chemically altered" through processing, the ingredient may be used in dietary supplements without further FDA notification or approval. Additionally, there are no current prohibitions or other FDA-initiated actions that suggest that Palo negro (as a whole leaf or extract) are not permitted for use in foods and/or dietary supplements.

Should you have any questions about FDA regulatory status of this ingredient, please do not hesitate to contact us at (305) 507-9843.

Sincerely,



Katherine L. Giannamore
Shehadeh Giannamore, PLLC

[4] 21 USC § 350b(a)(1).
[5] *Id*.