AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

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Re: Request for revision to online dietary supplement labeling guide

Hello Mr. Durkin and Dr. Welch -

I have recently been apprised of litigation that has been brought against marketers of dietary supplements over how the required statement of identity is presented on their supplement product labels, wherein state Attorneys General or private plaintiffs have alleged that such products, when labeled with the term "dietary supplement" on its own and with no modification, are noncompliant with federal labeling regulations. On at least two occasions these plaintiffs have cited guidance currently posted on FDA's website as the basis for this position.

I am therefore writing to direct your attention to this guidance, to express AHPA's view that the guidance in inaccurate in one detail, and to request the guidance be amended as described below.

The guidance at issue as found on FDA's website is titled "Dietary Supplement Labeling Guide: Chapter II. Identity Statement"[1] (dated April 2005). Specifically, Question 3 of the guidance currently reads as follows:

> "**3. Can the term "dietary supplement" by itself be considered the statement of identity?**
> No. This term by itself is not appropriately descriptive to be a statement of identity. 21 CFR 101.3(g)"

This response, however, is contrary to the relevant provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), to the language in FDA's preamble to the final rule that established the cited regulation, and to the cited regulation itself. These other references state the words "dietary supplement" on their own are sufficient as the statement of identity for a dietary supplement and also envision and allow but do not require modifications to this term.

[1] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm070594.htm; accessed August 27, 2015.

The relevant statutory provisions are as follows:

- Section 201(ff)(2)(C) of the FDCA[2] defines the term "dietary supplement" to include that such a product is "labeled as a dietary supplement."
- Section 403(s)(2)(B) of the FDCA[3] provides that a dietary supplement is misbranded if "the label or labeling of the dietary supplement fails to identify the product by using the term 'dietary supplement,' which term may be modified with the name of such an ingredient." The context of this provision informs that "such an ingredient" as that term is used here means a dietary ingredient as described in FDCA § 201(ff).

Thus, the relevant statutory language clearly allows use of the term "dietary supplement" on its own as the statement of identity on the label of a dietary supplement, and also allows this term to be modified at the labeler's discretion.

The preamble to FDA's Final Rule[4] that established the current regulation on the statement of identity for dietary supplements, as codified at 21 CFR 101.3(g), also states the term "dietary supplement" on its own is an acceptable option for such products' statement of identity and also allows this term to be modified with an appropriate description term. The relevant language from the preamble is as follows (emphasis added):

> "The basic nature of a dietary supplement is that it is a dietary supplement. This is the point made in both sections 201(ff)(2)(C) and 403(s)(2)(B) of the act. … The agency notes that section 403(s)(2)(B) of the act states that the product shall be identified 'by using the term 'dietary supplement,' which term **may** be modified with the name of such an ingredient.' The agency interprets this provision to mean that the term 'dietary supplement' **may** be modified to include the name of a dietary ingredient or ingredients (e.g., 'Vitamin C Supplement'). Furthermore, to provide additional flexibility, an identifying term that describes the types of dietary ingredients contained in the product in appropriately descriptive terms (e.g., 'Multivitamin Supplement,' 'Herbal Supplement') **may** be used. … Accordingly, FDA is revising § 101.3(g) to provide that the term 'dietary supplement' **may** be modified by replacing the term 'dietary' with the name of a dietary ingredient or ingredients or an appropriately descriptive term indicating the type of dietary ingredients that are in the product."

In addition, the codified rule is equally explicit in allowing either the stand-alone term "dietary supplement" or some appropriate modification of that term (emphasis added):

> "Dietary supplements shall be identified by the term 'dietary supplement' as a part of the statement of identity, except that the word 'dietary' **may** be deleted and replaced by the name of the dietary ingredients in the product (e.g., calcium supplement) or an

[2] 21 USC §321(ff)(2)(C)

[3] 21 USC §343(s)(2)(B)

[4] Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation, 62 FR 49826 at 49827. September 23, 1997.

appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins)." 21 CFR 101.3(g).

The use of the word "may" as opposed to "shall" to explain the regulatory option to modify the term "dietary supplement" as the statement of identity for a dietary supplement must be read, in both the preamble to the above-cited final rule and in the regulation itself, as clearly establishing that use the term "dietary supplement" on its own wholly satisfies the requirement to provide a statement of identity for a supplement product.

AHPA therefore recommends and requests the answer to Question 3 in this guidance be changed to read as follows, where strikethrough text is proposed to be removed and bold underlined text is proposed to be added:

> "**3. Can the term "dietary supplement" by itself be considered the statement of identity?**
> ~~No~~ **Yes**. This term by itself is ~~not~~ appropriately descriptive to be a statement of identity. **The statement of identity for a dietary supplement may therefore either consist simply of the term 'dietary supplement' or another appropriately descriptive term identifying the contents of the product, such as 'calcium supplement,' 'herbal supplement, or 'herbal supplement with vitamins"**.
>
> 21 CFR 101.3(g)"

AHPA will appreciate your attention to this matter at your earliest convenience. Please let me know if you need additional clarification or information or if you would like to discuss this in further detail.

Sincerely,

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