May 22, 2022

Senator Patty Murray
Chair, U.S. Senate HELP Committee
154 Russell Senate Office Building
Washington, DC 20510

Senator Richard Burr
Ranking Member, U.S. Senate HELP Committee
217 Russell Senate Office Building
Washington, DC 20510

Via email: helpuserfeebill@help.senate.gov

Re: Feedback on FDA Safety and Landmark Advancements (FDASLA) Act Discussion Draft

Honorable Senators Murray and Burr,

This letter serves to provide feedback of the American Herbal Products Association (AHPA)[1] on the discussion draft of the FDA Safety and Landmark Advancements (FDASLA) Act issued by the Senate HELP Committee on May 17, 2022. This feedback is limited to Sec. 811 ("Regulation of Dietary Supplements"), as proposed in Title VIII, Subtitle B of the FDASLA discussion draft. Also, given the short (5 day) time provided for feedback, it is possible that this letter has not addressed every issue of interest to AHPA's members.

Mandatory product listing should not be required for dietary supplements

AHPA staff have met with Senate HELP staff (both Majority and Minority) on a number of occasions to communicate AHPA's view that the U.S. Congress should not establish mandatory product listing (MPL) for dietary supplements as well as to further communicate its views that MPL is unnecessary, is redundant to current authorities of the U.S. Food and Drug Administration (FDA), is likely to fail to address any of FDA's actual regulatory needs, and will almost inevitably reduce access by American citizens to a broad range of safe dietary supplement products. This letter, however, is not the best forum for AHPA to restate its previously communicated views in detail; AHPA staff can be available on request to review and discuss these matters if the Senate HELP Committee continues to have an interest in hearing such views.

[1] AHPA is the national trade association and voice of the herbal products industry. AHPA's members include domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters, and distributors of herbs and herbal products as well as other dietary supplement products. AHPA's members are engaged in the commerce of herbs, herbal products, and other natural products marketed in a variety of sectors, including as foods, dietary supplements, drugs, and cosmetics.

If MPL is retained in the FDASLA compliance should be greatly simplified

AHPA restates here its position that the U.S. Congress should not establish an MPL requirement for dietary supplements for the reasons described in summary above. If, however, such a requirement is established under the FDASLA, AHPA strongly encourages the Senate HELP Committee to draft legislation that would limit compliance to require submission to FDA of only (1) identification of and contact information for the responsible person and the associated owner, operator or agent in charge (if a domestic firm) or U.S. agent (if a foreign entity), and (2) product labels.

This suggestion to simplify any eventual compliance requirements is specifically relevant to the proposed amendment to the Federal Food, Drug, and Cosmetic Act (FD&CA) identified in the discussion draft as new Section 403D (hereinafter 21 U.S.C. 343–3).

In making this suggestion for a simplified process, AHPA notes that submission to FDA of the above described identification and contact information would completely meet the requirements identified in proposed 21 U.S.C. 343–3(b)(1)(B), (C) and (D). AHPA notes also that submission of product labels would, except for one detail, completely meet the requirements identified in proposed 21 U.S.C. 343–3(b)(1)(A), (E), (F), (G), (H), (I), (J) and (K), because all of the information that would be required to be provided under these several paragraphs is already on each dietary supplement product label.

By way of illustration:

- Proposed 21 U.S.C. 343–3(b)(1)(A) would require "Any name of the dietary supplement and the statement of identity, including brand name and specified flavors, if applicable;" *this information is already included on each dietary supplement product label*.
- Proposed 21 U.S.C. 343–3(b)(1)(E) would require "A list of all ingredients in each such dietary supplement required under sections 21 101.4 and 101.36, title 21, Code of Federal Regulations (or any successor regulations) to appear on the label of a dietary supplement, including—(i) where applicable, ingredients in a proprietary blend as described in section 101.36(c) of title 21, Code of Federal Regulations (or any successor regulations); (ii) the amount per serving of each listed dietary ingredient; (iii) if required by section 101.36 of title 21, Code of Federal Regulations (or any successor regulations), the percent of the daily value of each listed ingredient; and (iv) the amount per serving of dietary ingredients within a proprietary blend;" *with the exception of paragraph (E)(iv) of this paragraph (which disclosure AHPA opposes; see discussion below), this information is already included on each dietary supplement product label*.
- Proposed 21 U.S.C. 343–3(b)(1)(F) would require "The number of servings per container for each container size;" *this information is already included on each dietary supplement product label*.
- Proposed 21 U.S.C. 343–3(b)(1)(G) would require "The directions for use;." *this information is already included on each dietary supplement product label*.

- Proposed 21 U.S.C. 343–3(b)(1)(H) would require "Warnings, notice, and safe handling statements, as required by section 101.17 of title 21, Code of Federal Regulations (or any successor regulations);" *this information is already included on each product label*.
- Proposed 21 U.S.C. 343–3(b)(1)(I) would require "Allergen statements for major food allergens (pursuant to sections 403(w) and 403(x);" *this information is already included on each dietary supplement product label*.
- Proposed 21 U.S.C. 343–3(b)(1)(J) would require "The form of the dietary supplement (such as tablets, capsules);" *this information is already included on each dietary supplement product label*.
- Proposed 21 U.S.C. 343–3(b)(1)(K) would require "Any health claims or structure or function claims;" *this information is already included on each dietary supplement product label*.

A preliminary cost analysis performed by AHPA estimates that the covered industry would need to spend at least $20 million to provide all of the detailed information identified in each of the above cited paragraphs, if submission comes to require manual data entry to a system created by FDA. AHPA assumes that this cost will be significantly less if listing can be accomplished simply by submitting labels to FDA, with no reduction in the product information received by the agency.

Quantitative information on ingredients in proprietary blends must not be required

AHPA restates here its position that the U.S. Congress should not establish an MPL requirement for dietary supplements. If, however, such a requirement is established under the FDASLA, AHPA and its members are strongly opposed to any statutory requirement to disclose under such a system "the amount per serving of dietary ingredients within a proprietary blend," as would be required under proposed 21 U.S.C. 343–3(b)(1)(E)(iv). Such information is generally considered to be important intellectual property owned by a dietary supplement company and thus has significant economic value.

In addition, AHPA notes that FDA can already obtain this information if needed for any regulatory purpose, as the agency can access dietary supplement manufacturing records during facility inspections.

FDA must not be permitted to reject listing submissions

AHPA restates here its position that the U.S. Congress should not establish an MPL requirement for dietary supplements. If, however, such a requirement is established under the FDASLA, the legislation should be worded to ensure in no uncertain terms and in language that cannot be subject to later reinterpretation that the agency cannot refuse acceptance of a product listing submission for any reason whatsoever.

A public-facing database of dietary supplement labels should not be authorized or created

FDA has existing authority to obtain dietary supplement labels, and FDA staff has at times informed AHPA that the agency is in possession of many such labels. Yet FDA has not to date identified any need or obligation to organize the labels now in its possession into a publicly available database, as envisioned in proposed 21 U.S.C. 343–3(c)(2).

AHPA restates here its position that the U.S. Congress should not establish an MPL requirement for dietary supplements. If, however, such a requirement is established under the FDASLA, the legislation should not force creation of a publicly available database of the records submitted under any eventual MPL requirement. AHPA is concerned that creation of such an "official" database will almost certainly be abused by opportunistic private plaintiffs.

In support of the view expressed here, AHPA notes that Subtitle A of the discussion draft, relating to cosmetics regulation, includes a product listing requirement for cosmetic products, but does not authorize the creation of a publicly accessible database of cosmetics products. AHPA sees no additional utility, and significantly increased regulatory cost for FDA, in the creation and upkeep of a publicly available database for dietary supplement products.

In addition, the National Institutes of Health maintains a Dietary Supplement Label Database (DSLD), which collects dietary supplement labels through the national census process as well as through voluntary submissions. This database currently lists 91,889 dietary supplement products as "on market." There is no benefit in spending additional taxpayer dollars in duplicating the expenses of this system. Because this database does not represent listed products as compliant with a statutory MPL requirement (i.e., it is "unofficial"), the abuse concern identified above does not extend to the DSLD.

Other revisions to the FD&CA would more meaningfully support the American public

In spite of AHPA's expressed view herein that the U.S. Congress should not establish an MPL requirement for dietary supplements, AHPA has identified other legislative priorities that would, if adopted as amendments to the FD&CA, advance the health of American citizens by providing better education for and access to safe dietary supplements. These include:

- Supplement education for consumers. Current restrictions on dissemination of truthful and non-misleading information about dietary supplements by marketers should be removed, including in online commerce. This would require an amendment to 21 U.S.C. § 343-2.
- Revisiting supplement ingredient market restrictions. The prior drug exclusion provision at 21 U.S.C. § 321(ff)(3)(B) excludes from the federal definition of a "dietary supplement" any "article" approved or authorized for investigation as a new drug (under certain broad conditions), and this exclusion is permanent. This provision should be amended to place a time limit on this restriction when the subject article is a dietary ingredient as described at 21 U.S.C. § 321(ff)(1), including, for example, a vitamin, a mineral, or an herb or other botanical.

- Definition of "chemical alteration" as applied to dietary ingredients. The FD&CA establishes certain requirements for any ingredient defined as a "new dietary ingredient" at 21 U.S.C. § 350b(d), and differentiates these requirements if the ingredient is "an article used for food in a form in which the food has not been chemically altered" (21 U.S.C. § 350b(a)(1)). But the term "chemically altered" is not defined by statute, leading to uncertainty as to the application of this provision. Congress should therefore create a statutory definition for the term "chemically altered" to establish that subjecting ingredients present in the food supply to traditional food manufacturing or preparation processes, such as filtration and cooking, does not constitute chemical alteration.

AHPA therefore recommends that the Senate HELP Committee consider a more patient and transparent approach to amending the FD&CA as it affects dietary supplements, by taking into account these suggestions and others that have been, or may come to be, presented by diverse stakeholders. The idea that the only mechanism that can be used by the U.S. Congress to improve dietary supplement laws is by attaching limited legislative proposals to must-pass legislation should be set aside to allow for a more thoughtful process that would provide a better opportunity to more thoroughly improve the regulation of dietary supplements.

Feedback on specific language in the discussion draft

In addition to the above stated overview positions, AHPA offers the following feedback on specific language in Sec. 811 of the FDASLA discussion draft:

- Page 117, line 3 re: proposed 21 U.S.C. 343–3(b)(1). Any information required for submission should be limited to information included on the product label and exclusive of, for example, product claims that appear in other marketing or labeling material.
- Page 117, lines 15-18 re: addresses of "all" locations. It is unclear from the language in the discussion draft whether companies would be required to provide identifying information for contracted entities that manufacturer, package, label or hold the companies products, or for any downstream distributors or retailers. These details should be clarified. In addition, in the event that the final bill requires FDA to create a publically accessible database in which MPL submissions will be posted, there are significant concerns about disclosing trade agreements related to contract manufacturers and distributors, which are generally considered to be confidential.
- Page 119, lines 3-6 and page 121, line 21 through page 122, line 10 re: "listing numbers." The single most point of confusion communicated to date by AHPA members has been in relation to the "listing number" as described in the discussion draft. Questions include: Is the listing number required to be included on product labels?; On the other hand, is it allowed or prohibited to be listed on product labels?; Isn't it a circular requirement that listing cannot be accomplished prior to having a listing number, but a listing number may not be available until after the listing is submitted?; Even though FDA would be required to provide a process for companies to reserve listing numbers in advance of listing, what will happen if FDA sets a quantitative limit on the number of such pre-listing numbers allowed that is insufficient for an individual

company's listing requirements? Are there any situations in which FDA would be authorized to refuse to provide a listing number, if the agency views the listing not to be "complete"? AHPA strongly encourage the Senate HELP Committee to remove any uncertainty on this detail prior to trying to move this legislation.

- Page 119, lines 7-9 re: format. AHPA has limited confidence that FDA will create an electronic format for listing that will be easy to use and would minimize administrative burdens on the regulated trade. AHPA is also concerned that FDA might be tempted to use any electronic format as a way to "encourage" or identify "optional" information for inclusion in a listing that would go beyond Congressional intent. AHPA notes also that, should Senate HELP accept the recommendation above that submission of labels should be all that is required to meet any eventual listing requirement, the "format" described here will not be necessary.
- Page 119, lines 10-13 re: FDA's notification of receipt of a listing. AHPA notes there is no time requirement here, other than "upon receipt" of a listing, and suggests that a specific time (e.g., "immediately" if the listing system is automated and properly designed; alternately, "within one business day") be established for this notification.
- Page 119, line 18 and page 122, line 4 re: proposed 21 U.S.C 343–3(b)(3) and (c)(1). The term "additive" has no clear meaning in this context and thus either should be defined for these purposes, replaced with another term, or omitted so as to leave no ambiguity regarding what products will require separate listings.
- Page 120, line 9 re: proposed 21 U.S.C 343–3(b)(4)(A)(ii). For "new dietary supplements" introduced into interstate commerce after the date of enactment, the responsible person should be allowed to submit product listings within 120 days of market entry, as is applicable to cosmetics products as would be established under Subtitle A section 607(c)(2) of the discussion draft at page 96, line 24. Similarly, listings for reformulated products should be submitted annually as per the cosmetics provision at (c)(5), page 98, line 13, rather than prior to market introduction.
- Page 121, lines 3-10 re: changes to a currently listed product. It is not uncommon for a dietary supplement product that is reformulated to be simultaneously in the market in its original formulation and its revised formulation. This provision does not appear to have addressed this detail.
- Page 123, lines 16-22 re: guidance on NDI notifications and related issues. AHPA has requested FDA consider issuance of the described guidance in several sections to address separate and discrete topics where guidance may be needed, rather than as a single guidance document. FDA in January 2022 issued information on its Foods Program Guidance Under Development, in which the agency identified two separate topics related to NDI guidance. To support FDA's current process in NDI guidance development, AHPA suggests placement of the words "at least partial" between the words "shall publish" and the words "final guidance" on page 123, line 18.
- Page 124, lines 13-20 re: creation of a new prohibited act at 21 U.S.C. § 331. AHPA supports in concept the idea that a new prohibited act may provide a useful tool for FDA to enforce against, and remove from the market, products that masquerade as dietary supplements but contain undeclared active pharmaceutical ingredients or other unlawful ingredients. However, AHPA believes that proposed 21 U.S.C. § 331(hhh) will not be effective for this purpose. AHPA has observed that many such products do not

bear label statements that define the products as dietary supplements, so that the agency may not be able to readily establish that any such product is, in fact, "marketed as a dietary supplement." AHPA has developed draft alternative language that may be more effective in achieving the desired purpose of this proposed amendment to 21 U.S.C. § 331 and can share that draft language with Senate HELP staff if of interest.

AHPA greatly appreciates the opportunity to provide feedback on the FDASLA discussion draft and will continue to be engaged with this process, including by continued direct communications with Senate HELP staff if requested.

Sincerely,

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