AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

September 24, 2018

Board Members
Arizona State Board of Pharmacy
1616 W. Adams St., Suite 120
Phoenix, AZ 85007

c/o Kam Gandhi, PharmD
Executive Director
Arizona State Board of Pharmacy
Via email: kgandhi@azpharmacy.gov

RE: Permits under the Arizona Pharmacy Act should not be required for dietary supplements

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Dear Dr. Gandhi,

I am addressing this letter to all of the current Members of the Arizona State Board of Pharmacy and directing it to you with a request that you forward it to the current Board timely for its meeting on September 26-27, 2018.

The contents of this letter are relevant both generally with regard to permits under the State of Arizona's regulations as stipulated in the Arizona Pharmacy Act and codified in Arizona Administrative Code, Title 4, Chapter 23; and specifically with regard to the agenda of the meeting of the Board scheduled on September 26-27, 2018, and particularly to item 21.b. on that agenda ("Discussion, consideration and possible action - The Himalaya Drug Company's nonprescription wholesaler application").

The American Herbal Products Association (AHPA) is the national trade association representing the herbal products industry. AHPA is comprised of companies doing business as manufacturers and marketers of herbs and herbal products, including herbal dietary supplements, as well as other dietary supplement products. Several AHPA members maintain operations in the State of Arizona and many others sell their dietary supplements to consumers in Arizona.

AHPA understands that Himalaya Drug Company submitted an application to the Board for a permit as a nonresident wholesaler of nonprescription drugs and has now requested this application be withdrawn as erroneously submitted. AHPA agrees that this application should not have been submitted, since Himalaya does not, in fact, distribute any nonprescription drugs as defined under Federal or Arizona State laws, and therefore requests the board accept Himalaya's request to withdraw its application.

AHPA also understands that the Arizona State Board of Pharmacy (the Board) has recently taken the position that each company that offers dietary supplements for sale within the State is now required to register as a wholesaler of nonprescription drugs, and more specifically, as a resident wholesaler of nonprescription drugs if the company is located in the State, or as a nonresident wholesaler of nonprescription drugs if the company is located outside of Arizona, if any of the dietary supplements offered by the company for sale in Arizona provide in labeling a statement of nutritional support. AHPA further understands that this position is based on a recent interpretation of the Arizona Pharmacy Act (Arizona Revised Statutes – Pharmacy Act: Title 32 – Chapter 18; hereinafter the AZ Pharmacy Act or ARS 32) whereby the Board considers any dietary supplement that bears such labeling to be a nonprescription drug as that term is defined in the AZ Pharmacy Act.

AHPA strongly opposes this interpretation by the Arizona State Board of Pharmacy of the Arizona Pharmacy Act, and believes this interpretation to be incorrect, and therefore opposes the position of the Board that permits are required for companies that manufacture or offer such dietary supplement products for sale in the State of Arizona.

Here follows AHPA's analysis in support of this stated opposition to the Board's interpretation that the AZ Pharmacy Act requires permits for lawfully labeled dietary supplement products manufactured or marketed in Arizona.

Dietary supplements are regulated by FDA

Federal law requires companies that manufacture, pack, label or hold (except at retail) dietary supplement products to register as food facilities with the U.S. Food and Drug Administration (FDA), and to meet stringent requirements for current good manufacturing practice; product labeling and claims; submission of reports received of serious adverse events associated with product use; and for other purposes.

Dietary supplements are not nonprescription drugs under the AZ Pharmacy Act

The AZ Pharmacy Act defines "nonprescription drug" (or "over-the-counter drug") to mean (with certain exceptions not relevant to this discussion):

> "*…any nonnarcotic medicine or drug that may be sold without a prescription and is prepackaged and labeled for use by the consumer in accordance with the requirements of the laws of this state* **and** *federal law*" (emphasis added). ARS 32-1901 (56).

This language thus dictates that for a product to meet the State's definition of a "nonprescription drug" its labeling must be in accordance with both Arizona and Federal law.

There are, however, no dietary supplements that are labeled in compliance with the Federal law for labeling of nonprescription drug products. Federal labeling law for all such drug products requires, among other details, inclusion of a "Drug Facts" panel in the products' labeling. 21 CFR 201.66. On the other hand, Federal labeling law for dietary supplements requires, among other details, these products to be labeled with the inclusion of a "Supplement Facts" panel. 21 CFR 101.36.

Thus, there is no dietary supplement product sold in the State of Arizona (or elsewhere in the United States) that can meet the AZ Pharmacy Act's definition of "nonprescription drug," since it is not possible for such products to labeled in accordance with the Federal law for labeling nonprescription drug products.

Lawfully labeled dietary supplements are not drugs under Federal law and should not be treated as drugs under the AZ Pharmacy Act

The AZ Pharmacy Act defines "drug" to mean:

> *"(a) Articles recognized, or for which standards or specifications are prescribed, in the official compendium.*
> *"(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in the human body or other animals.*
> *"(c) Articles other than food intended to affect the structure or any function of the human body or other animals.*
> *"(d) Articles intended for use as a component of any articles specified in subdivision (a), (b) or (c) of this paragraph but does not include devices or their components, parts or accessories.*" ARS 32-1901 (29).

AHPA notes there are significant differences between Arizona's definition of "drug" and the Federal definition of this term, as set out in the Federal Food, Drug and Cosmetic Act (FDCA), as follows:

> "*(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and*
> *"(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and*
> *"(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and*
> *"(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).*
>
> *"A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title* **is not a drug** *solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title* **is not a drug** *under clause (C) solely because the label or the labeling contains such a statement"* (emphasis added). 21 U.S.C. 321(g)(1).

It is readily seen that paragraphs (a)/(A) through (d)/(D), respectively, of each of the above definitions have essentially the same meaning, so there is no meaningful difference between the definitions of the term "drug" under the AZ Pharmacy Act and the FDCA insofar as these paragraphs are concerned. The difference between these definitions is in the additional paragraph in the FDCA definition.

This additional paragraph represents revisions to the Federal definition of "drug" brought about by two very significant amendments to the FDCA: the Nutrition Labeling and Education of 1990 (NLEA)[1] and the Dietary Supplement Health and Education Act of 1994 (DSHEA).[2]

NLEA amended the FDCA in many details, including amending the definition of "drug" by allowing certain claims to be made for foods that would previously have established the foods to be regulated as drugs. Specifically, NLEA added § 343(r)(1)(B) to the FDCA,

[1] Public Law 101-535.

[2] Public Law 103-417.

which allows certain claims that characterize the relationship of certain nutrients "to a disease or a health-related condition." FDA currently describes NLEA-authorized health claims as those which "characterize a relationship between a food, a food component, or dietary ingredient and **risk of a disease**" (emphasis added), and provides as one example, "adequate calcium throughout life may reduce the risk of osteoporosis."[3]

Prior to the NLEA amendment to FDCA's definition of "drug," a product labeled to bear an NLEA-authorized health claim would have been considered to be a drug, intended to "prevent" disease in accordance with paragraph (b)/(B) of the definitions of "drug" under the AZ Pharmacy Act and the FDCA, respectively. But NLEA specifically and clearly amended the FDCA to state that a food that bears such a health claim "is not a drug."

Similarly, DSHEA amended the FDCA in many details, including amending the definition of "drug" by allowing certain claims to be made for dietary supplements that would previously have established the supplements to be regulated as drugs. Specifically, DSHEA added § 343(r)(6) to the FDCA to allow certain truthful, not misleading, and substantiated statements to be made in the labeling of dietary supplements. Such a statement may include one that "claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient."

Prior to the DSHEA amendment to FDCA's definition of "drug," a product labeled to bear certain of the DSHEA-authorized statements could have been considered to be a drug if intended to "to affect the structure or any function of the body of man or other animal" in accordance with paragraph (c)/(C) of the definitions of "drug" under the AZ Pharmacy Act and the FDCA, respectively. But DSHEA specifically and clearly amended the FDCA to state that a supplement that bears such a statement "is not a drug."

Notably, the AZ Pharmacy Act has not been amended to be consistent with the FDCA with regard to the amendments made by NLEA and DSHEA to the Federal definition of the term "drug" under the FDCA. Nonetheless, to the best of AHPA's knowledge the

[3] Accessed on September 24, 2018 at https://www.fda.gov/food/labelingnutrition/ucm111447.htm.

Board does not consider food or supplement products labeled with an NLEA-approved health claim to be drugs under the State's laws.

To be consistent, the Board must interpret the AZ Pharmacy Act either to mean that both NLEA-authorized health claims and DSHEA-authorized statements constitute drug claims, and therefore cause products that bear such claims or statements to be drugs, such that any manufacturer or wholesaler of these must obtain a permit from the Board, or that neither of these types of claims constitute drug claims or establish Board permit requirements. AHPA strongly recommends the Board adopt the latter option.

Requiring nonresident nonprescription drug wholesale permits for companies located outside of Arizona in order to sell dietary supplements in the State of Arizona will set requirements that cannot be met by companies located in other states

The Arizona Administrative Code (AAC), Title 4, Chapter 23 ("Board of Pharmacy") identifies specific requirements for applicable nonresident permits, including nonresident nonprescription drug wholesale permits. These requirements include, among others, possessing "a current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides." AAC R4-23-607 (A)(2). Similarly, the code specifies that at the time of application for such a permit and in order to obtain a nonresident nonprescription drug wholesale permit the applicant must complete an application that includes submission of "[a] copy of the applicant's current equivalent license or permit, issued by the licensing authority in the jurisdiction where the person or firm resides and required by subsection (A)(2)." AAC R4-23-607 (B)(5).

These requirements set up an impossible situation for dietary supplement companies located outside of Arizona. Because these products are not nonprescription drugs, there is no reason for these firms to possess a license or permit issued by the State in which they reside that is equivalent to Arizona's nonprescription drug permit, and to the best of AHPA's knowledge, there is no other State that issues such a license or permit.

Classifying dietary supplements as nonprescription drugs will place new burdens on manufacturers, wholesalers and retailers of dietary supplements, including resident and nonresident firms

Should the Board go forward with its interpretation that the definition of "drug" under the AZ Pharmacy Act includes dietary supplements that are labeled with DSHEA-authorized statements, and that such products are "nonprescription drugs" under the AZ Pharmacy Act, such a decision, if consistently applied, will impact not only companies

that reside outside of the State but also all supplement manufacturers and wholesalers located in Arizona, as well as every retail location in the State that sells such dietary supplements, as each of these would apparently be required to retain one or another nonprescription drug permits to operate within the State.

Under AAC Title 4, Chapter 23, Article 6 ("Permits and Distribution of Drugs"), permits are required, as is extensive recordkeeping, for both resident and nonresident firms that manufacture or offer for sale nonprescription drugs, as well as for retail locations in Arizona that sell or distribute nonprescription drugs. These include:

- Arizona resident nonprescription drugs retailers, including groceries, other non-pharmacy retail outlets, and mobile or non-fixed location retailers. AAC R4-23-603. Note that dietary supplements are sold in many such locations in the State of Arizona.
- Arizona resident nonprescription drug manufacturers. AAC R4-23-604. Note there are numerous dietary supplement manufacturers in the State of Arizona.
- Arizona resident nonprescription drug wholesalers. AAC R4-23-605.
- Nonresident nonprescription drug firms, including manufacturers and wholesalers. AAC R4-23-607.

Thus, if the Board persists in its interpretation to include dietary supplements that bear DSHEA-authorized claims in the State's definition of "drug," and applies the permit regulations for nonprescription drugs consistently to all companies that manufacture and sell these products, many manufacturers and wholesalers, both within the State of Arizona and that reside in other States, will be burdened with compliance with the permit and recordkeeping regulations laid out in AAC Title 4, Chapter 23, Article 6. In addition, and almost certainly of greater concern, every retail location in Arizona in which dietary supplements are sold would apparently need to obtain a permit under AAC R4-23-603.

AHPA strongly opposes any such interpretation and the attendant imposition of new regulatory burdens on all or virtually all dietary supplement companies operating in the State of Arizona.

In addition, AHPA strongly encourages the Board to give due consideration to the potential new burdens on so many dietary supplement businesses, including many such businesses that have principal offices or locations in Arizona, if the Board begins to

consistently apply an interpretation of the term "drug" as defined in the AZ Pharmacy Act as inclusive of dietary supplements that bear DSHEA-authorized statements.

AHPA notes that, according to data issued by FDA, approximately 89 percent of all dietary supplement companies are small businesses with less than 500 employees, including over 50 percent that are very small businesses with less than 20 employees.[4] Thus whatever new burdens are placed on dietary supplement companies if the Board treats these as nonprescription drug companies under the AZ Pharmacy Act and related rules will fall largely on small and very small businesses.

Thus, the new burdens that will be created on companies that sell dietary supplements in Arizona by the Board's interpretation to regulate many supplement products as nonprescription drugs will fall primarily on small businesses, including many small businesses in Arizona. The Board therefore must consider other Arizona statutes, regulations and programs relevant to small businesses.

Specifically and as one example, AHPA notes that Arizona's Small Business Bill of Rights[5] ensures significant rights to small businesses "to ensure fair and open regulation by state agencies."

One such right, presented here as just one example of the rights bestowed on small businesses by this statute, is that small business "may expect state agencies to avoid duplication of other laws that do not enhance regulatory clarity and to avoid dual permitting to the extent practicable," unless specifically authorized by statute.[6] Because every dietary supplement company that does business in Arizona is already required to maintain registration as a food facility with FDA, the Board's efforts to also obtain permits for such firms to operate in the State of Arizona based on its interpretation that supplements are nonprescription drugs clearly constitutes a "dual permitting" burden.

AHPA has not completely reviewed Arizona's Small Business Bill of Rights in preparation of this communication to the Board, but strongly encourages the Board to do so on its own initiative.

[4] 72 FR 34751 at 34938.

[5] ARS 41-1001.01.

[6] ARS 41-1001.01(19).

Finally, AHPA also strongly recommends the Board evaluate its new interpretation of the term "drug" as defined in the AZ Pharmacy Act as inclusive of dietary supplements that bear DSHEA-authorized statements, and the attendant new regulatory burdens such an interpretation will impose on Arizona businesses, in reference to Arizona Governor Doug Ducey's "Regulation Rollback" program. The Governor's Office describes this program as "…a strategic step … to make Arizona the best state in the nation to open a new business or to expand an existing one." The Office also reports that the Governor has stated, "…our small businesses have to deal with an array of burdensome regulations 'just because they're on the books and nobody's bothered to change them.'"[7]

In AHPA's view the Board's recent interpretation that the term "drug" as defined in the AZ Pharmacy Act to include dietary supplements that bear DSHEA-authorized statements goes in exactly the opposite direction than the Governor's "Regulation Rollback" program. This interpretation is not a regulation that has been "on the books," and in fact, the Board is now "bother[ing] to change them" for the worse, from the perspective of burdensome regulations that is contrary to the Governor's stated interest in opening or expanding businesses in the State of Arizona.

The Board should provide an opportunity for public notice and comments if it decides (or has decided) to revise its interpretation of the Act's definition of nonprescription drugs to include dietary supplements

A decision by the Board to interpret the AZ Pharmacy Act's definition of "drug" to include dietary supplements that bear DSHEA-authorized statements would represent a significant revision to how these products are regulated in the State of Arizona. Although this revised or new interpretation may not constitute formal rulemaking, its impact on the dietary supplement industry will create significant new regulatory burdens on this industry.

AHPA therefore strongly recommends and requests that, if this is the will of the Board, such a decision be accomplished through a rulemaking proceeding to amend the Board of Pharmacy regulations during which all stakeholders would have an opportunity to make their views known, including dietary supplement companies located in Arizona and otherwise doing business in Arizona.

[7] Accessed on September 24, 2018 at https://azgovernor.gov/redtape.

Conclusions

AHPA has stated in this letter its strong recommendation that the Arizona Board of Pharmacy reconsider its recent interpretation of the definition of "drug" under the AZ Pharmacy Act in a manner that includes dietary supplements labeled with a DSHEA-authorized statement, and the attendant purported requirement for companies that manufacture or sell such supplement products in the State of Arizona, including at retail, to obtain a permit under AAC R4-23-601 *et seq.* and to comply with the extensive associated recordkeeping requirements.

AHPA has also provided here thorough support for this recommendation, and therefore requests the Board to accept this recommendation and recognized that such supplements are not, in fact, nonprescription drugs.

Such Arizona permits and recordkeeping requirements, if the Board does not accept AHPA's recommendation and request, would be unprecedented in the United States. Establishing such requirements for such dietary supplements would have a substantial adverse impact on an industry that has a strong positive effect on the economy of Arizona. AHPA has several members that reside in Arizona or sell products into Arizona who would be adversely affected by the policy being considered.

Thank you very much to your attention to these comments of the American Herbal Products Association.

Sincerely,
Michael McGuffin

President, AHPA
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