Docket No. USTR-2019-0004

#### BEFORE

#### The OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

COMMENTS OF THE

#### AMERICAN HERBAL PRODUCTS ASSOCIATION

#### ON THE

#### PROPOSED MODIFICATION OF ACTION PURSUANT TO SECTION 301: CHINA'S ACTS, POLICIES, AND PRACTICES RELATED TO TECHNOLOGY TRANSFER, INTELLECTUAL PROPERTY, AND INNOVATION

June 17, 2019

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## Prefatory remarks

On May 17, 2019 the Office of the United States Trade Representative (USTR or the Trade Representative) published a Federal Register notice (the May 17 Notice<sup>1</sup>) in which the Trade Representative proposed a modification of actions already being taken in the investigation conducted under section 301 of the Trade Act of 1974 (the Trade Act) of the acts, policies, and practices of the Government of China related to technology transfer, intellectual property, and innovation (the Section 301 Investigation). The May 17 Notice described the proposed modification as an additional *ad valorem* duty<sup>2</sup> of 25 percent on a list of certain products from China set out in an Annex to the May 17 Notice (the Proposed Product List). The Proposed Product List identified products from China classified in 3,805 full or partial tariff subheadings of the Harmonized Tariff Schedule of the United States (HTSUS) estimated to have a value of \$300 billion.

Previously issued Federal Register notices related to USTR actions to apply *ad valorem* tariffs on certain Chinese exports in response to the Section 301 Investigation provided explanations for how the lists of specific HTSUS subheadings included were developed.

For example, a notice issued on April 6, 2018 (the April 6 Notice) that identified products from China classified in a list of 1,333 tariff subheadings of the HTSUS estimated to have a value of \$50 billion described a methodology for identifying the specific HTSUS subheadings as including:

"The list ... [removed] specific products identified by analysts as likely to cause disruptions to the U.S. economy, and tariff lines that are subject to legal or administrative constraints [and was] ... compiled by selecting products ... with lowest consumer impact." <sup>3</sup>

<sup>3</sup> 83 FR 14906 at 14907.

<sup>&</sup>lt;sup>1</sup> 84 FR 22564.

<sup>&</sup>lt;sup>2</sup> In a related Federal Register notice USTR explained this to mean that current duties, if any, would be increased by 25 percent (absolute rather than relative) and provided the following examples: "For example, if a good of Chinese origin is currently subject to a zero *ad valorem* rate of duty, the product would be subject to a 25 percent *ad valorem* rate of duty; if a good of Chinese origin were currently subject to a 10 percent *ad valorem* rate of duty, the product would be subject to a 35 percent *ad valorem* rate of duty; and so on." 83 FR 14906 at 14907.

Similarly, a notice issued on July 17, 2018 (the July 17 Notice) that identified products from China classified in a list of 6,031 tariff subheadings of the HTSUS estimated to have a value of \$200 billion described a methodology that USTR had used for identifying the specific HTSUS subheadings proposed to be subject to an *ad valorem* tariff as including:

"The selection process took account of likely impacts on U.S. consumers, and involved the removal of subheadings identified by analysts as likely to cause disruptions to the U.S. economy, as well as tariff lines subject to legal or administrative constraints." <sup>4</sup>

Unlike the two earlier Federal Register notices cited above, the May 17 Notice did not provide a similar description of the methodology or process USTR used to identify the products in the Proposed Product List included as an Annex to that notice.

It should be noted, however, that, in the request for comments that accompanied the May 17 Notice, USTR specifically requested that commenters address, among other things, whether imposing increased duties on a particular product identified in the Proposed Product List would cause disproportionate economic harm to U.S. interests, including small or medium-sized businesses and consumers.

The American Herbal Products Association (AHPA) acknowledges and appreciates the Trade Representative's attention on assurance that actions taken by USTR in response to the Section 301 Investigation do not cause disproportionate economic harm to U.S. businesses, and that consideration is given to likely impacts on U.S. consumers. AHPA views this attention and consideration as consistent with the Congressional Statement of Purpose of the Trade Act, which states, in relevant part to these comments, purposes including "to foster the economic growth of and full employment in the United States…"<sup>5</sup> and "…to assist industries, firm[s], workers, and communities to adjust to changes in international trade flows."<sup>6</sup>

<sup>4 83</sup> FR 33608 at 33610.

<sup>&</sup>lt;sup>5</sup> 19 U.S.C. 2102(1).

<sup>&</sup>lt;sup>6</sup> 19 U.S.C. 2102(4).

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 as foods, dietary supplements, drugs, cosmetics, and other types of products in the United States and in other countries. Many AHPA members use ingredients that are produced in and exported from China in their products. These comments are therefore submitted on behalf of AHPA's members.

# Overview and summary of points

AHPA is requesting in these comments that USTR remove from the Proposed Product List and exclude from any resultant final list all of the HTSUS subheadings listed in the Annex in the May 17 Notice and identified in these comments as relevant to companies in the dietary supplement and herbal products industry that manufacture or market their products in the United States.

AHPA believes this request is firmly grounded in the Congressional Statement of Purpose that accompanies the Trade Act of 1974, which statute is the basis for the action proposed in the May 17 Notice. This Congressional statement asserts, in relevant part to these comments, the purposes of the Trade Act to include "to foster the economic growth of and full employment in the United States…" and "…to assist industries, firm[s], workers, and communities to adjust to changes in international trade flows." In AHPA's view, the effects on U.S. businesses and American consumers of this latest modification to USTR's actions in this matter, as described in the May 17 Notice, would be inconsistent with the intent of Congress in passing the Trade Act.

AHPA is providing here significant information in support of this request, including:

- The Proposed Product List will harm U.S. businesses and American consumers;
- U.S. companies that manufacture or market dietary supplement make significant contributions to the U.S. economy with jobs and taxes;

- The vast majority of U.S. dietary supplement companies are small businesses;
- Estimates of the costs that individual U.S. manufacturers and marketers of dietary supplements and other herbal products will bear from the proposed 25 percent *ad valorem* duty on the HTSUS subheadings identified in Proposed Product List can be assumed to be extensive, ranging as high as millions of dollars annually for some individual companies;
- U.S. manufacturers and marketers of products impacted by these proposed additional *ad valorem* duties will be faced with the need to either increase prices and thus risk sales losses, absorb additional costs by reducing profit margins, or discontinue products; each of these options risks economic harm to these companies and job losses to their employees;
- Inclusion of the identified HTSUS subheadings in the Proposed Product List will cause extensive disruptions in ingredient supply chains, which will require substantial resources and unacceptable time lapses to address;
- A significant portion of the American population use dietary supplements and other herbal products to promote their health, and these consumers will encounter increased prices or reduced selection, or both, if USTR goes forward with this action as proposed;
- Consideration should be given to excluding all ingredients used in dietary supplements and other foods in recognition of the important role these products play in promoting Americans' health;
- Harming U.S. businesses and American consumers is inconsistent with USTR's own criteria for selecting appropriate Chinese exports for imposition of duties in response to the Section 301 Investigation.

Detailed discussions follow on each of the points delineated above as supporting AHPA's request herein for removal of the identified HTSUS subheadings from the Proposed Product List.

# The Proposed Product List will harm U.S. businesses and American consumers

The Proposed Product List as published in the May 17 Notice identifies in its Annex a large number of HTSUS subheadings that include ingredients used in dietary supplements and other herbal products manufactured and marketed in the U.S.

Dietary supplements may include vitamins, minerals, herbs and other botanicals, amino acids, and numerous other natural substances, and many of these same ingredients are also used in other herbal products, such as teas, cosmetics, and other consumer products. Many such ingredients are imported from China for use by U.S. manufacturers and marketers of these products, and for many such ingredients China is the primary or only source.

The Proposed Product List in the May 17 Notice includes numerous commodities used in dietary supplement and other herbal products made and marketed in the U.S. and therefore of concern to AHPA's members. Examples include but may not be limited to the following:

- 0802.70.10 ...... Kola nuts (Cola spp.), fresh or dried, in shell.
- 0802.70.20 ...... Kola nuts (Cola spp.), fresh or dried, shelled.
- 0802.80.10 ...... Areca nuts, fresh or dried, in shell.
- 0805.50.20 ...... Lemons, fresh or dried.
- 0805.50.40 ...... Limes of the Citrus aurantifolia variety, fresh or dried.
- 0805.90.01 ...... Citrus fruit, not elsewhere specified or included, fresh or dried, including kumquats, citrons and bergamots.
- 0902.10.10 ...... Green tea in packages not over 3 kg, flavored.
- 0902.10.90 ...... Green tea in packages not over 3 kg, not flavored.
- 0902.20.10 ...... Green tea in packages over 3 kg, flavored.
- 0902.20.90 ...... Green tea in packages over 3 kg, not flavored.
- 0902.30.00 ...... Black tea (fermented) and partly fermented tea, in immediate packings of a content not exceeding 3 kg.
- 0902.40.00 ...... Black tea (fermented) and partly fermented tea, other than in immediate packings of a content not exceeding 3 kg.
- 0903.00.00 ..... Mate.
- 0904.11.00 ...... Pepper of the genus Piper, neither crushed nor ground.
- 0904.12.00 ...... Pepper of the genus Piper, crushed or ground.
- 0904.21.20 ...... Paprika, dried neither crushed nor ground.
- 0904.21.40 ...... Anaheim and ancho pepper, dried, neither crushed nor ground.
- 0904.21.60 ...... Fruits of the genus Capsicum, other than paprika or anaheim and ancho pepper, dried, not crushed or ground.
- 0904.21.80 ...... Fruits of the genus Pimenta (including allspice), dried.
- 0904.22.20 ...... Paprika, crushed or ground.
- 0904.22.40 ...... Anaheim and ancho pepper, crushed or ground.

- 0904.22.73 ...... Mixtures of mashed or macerated hot red peppers and salt, nesoi.
- 0904.22.76 ...... Fruits of the genus capsicum, crushed or ground, nesoi.
- 0904.22.80 ...... Fruits of the genus Pimenta (including allspice), crushed or ground.
- 0905.10.00 ...... Vanilla beans, neither crushed nor ground.
- 0905.20.00 ...... Vanilla beans, crushed or ground.
- 0906.11.00 ...... Cinnamon (Cinnamomum zeylanicum Blume) neither crushed nor ground.
- 0906.19.00 ...... Cinnamon and cinnamon-tree flowers, nesoi, neither crushed nor ground.
- 0906.20.00 ...... Cinnamon and cinnamon-tree flowers, crushed or ground.
- 0907.10.00 ...... Cloves (whole fruit, cloves and stems), neither crushed nor ground.
- 0907.20.00 ...... Cloves (whole fruit, cloves and stems), crushed or ground.
- 0908.11.00 ...... Nutmeg, neither crushed nor ground.
- 0908.12.00 ...... Nutmeg, crushed or ground.
- 0908.21.00 ...... Mace, neither crushed nor ground.
- 0908.22.20 ...... Mace, crushed or ground, Bombay or wild.
- 0908.22.40 ...... Mace, crushed or ground, other than Bombay or wild mace.
- 0908.31.00 ...... Cardamoms, neither crushed nor ground.
- 0908.32.00 ...... Cardamoms, crushed or ground.
- 0909.21.00 ...... Seeds of coriander, neither crushed nor ground.
- 0909.22.00 ...... Seeds of coriander, crushed or ground.
- 0909.31.00 ...... Seeds of cumin, neither crushed nor ground.
- 0909.32.00 ...... Seeds of cumin, crushed or ground.
- 0909.61.00 ...... Seeds of anise, badian, caraway or fennel; juniper berries; neither crushed nor ground.
- 0909.62.00 ...... Seeds of anise, badian, caraway or fennel; juniper berries; crushed or ground.
- 0910.11.00 ...... Ginger, neither crushed nor ground.
- 0910.12.00 ...... Ginger, crushed or ground.
- 0910.20.00 ...... Saffron.
- 0910.30.00 ...... Turmeric (curcuma).
- 0910.91.00 ...... Mixtures of spices.
- 0910.99.05 ...... Thyme; bay leaves, crude or not manufactured.
- 0910.99.06 ...... Thyme, other than crude or not manufactured.
- 0910.99.07 ...... Bay leaves, other than crude or not manufactured.

- 0910.99.10 ..... Curry.
- 0910.99.20 ...... Origanum, crude or not manufactured.
- 0910.99.40 ...... Origanum, other than crude or not manufactured.
- 0910.99.50 ..... Dill.
- 0910.99.60 ...... Spices, nesoi.
- 1212.94.00 ..... Chicory roots.
- 1301.20.00 ...... Gum Arabic.
- 1301.90.91 ...... Lac, natural gums, resins, gum-resins and oleoresins (e.g., balsams), nesoi.
- 1302.12.00 ...... Saps and extracts of licorice.
- 1302.13.00 ...... Saps and extracts of hops.
- 1302.14.01 ...... Vegetable saps and extracts of ephedra.
- 1302.19.41 ...... Ginseng and other substances having prophylatic or therapeutic properties.
- 1302.19.91 ...... Vegetable saps and extracts nesoi.
- 1302.31.00 ...... Agar-agar.
- 2101.12.90 ...... Preparations nesoi, with a basis of extracts, essences or concentrates or with a basis of coffee.
- 2101.20.20 ...... Extracts, essences or concentrates of tea or mate.
- 2101.20.32 ...... Preparations with a basis of extracts, essences or concentrates or with a basis of tea or mate, subject to general note 15 (outside quota)
- 2101.20.90 ...... Preparations nesoi, with a basis of extracts, essences or concentrates or with a basis of tea or mate.
- 2101.30.00 ...... Roasted chicory and other roasted coffee substitutes and extracts, essences and concentrates thereof.
- 2905.43.00 ...... Mannitol.
- 2905.44.00 ..... D-glucitol (Sorbitol).
- 2905.45.00 ..... Glycerol.
- 3301.12.00 ...... Essential oils of orange.
- 3301.19.10 ...... Essential oils of grapefruit.
- 3301.19.51 ...... Essential oils of citrus fruit, other, nesoi.
- 3301.24.00 ...... Essential oils of peppermint (Mentha piperita).
- 3301.25.00 ...... Essential oils of mints, other than peppermint.
- 3301.29.10 ...... Essential oils of eucalyptus.
- 3301.29.20 ...... Essential oils of orris.
- 3301.29.51 ...... Essential oils other than those of citrus fruit, other, nesoi.
- 3301.30.00 ...... Resinoids.

- 3301.90.10 ...... Extracted oleoresins consisting essentially of nonvolatile components of the natural raw plant.
- 3301.90.50 ...... Concentrates of essential oils; terpenic by-product of the deterpenation of essential oils; aqueous distillates & solutions of essential oils.

#### The dietary supplement industry provides U.S. jobs

Data on the economic impact of the U.S. dietary supplement industry were published in 2016 on behalf of the Council for Responsible Nutrition (the CRN Economic Study), a trade association that represents the dietary supplement industry.<sup>7</sup> According to this data, the dietary supplement industry, defined to include production, wholesaling and retailing of dietary supplements, in 2016 accounted for about \$121.59 billion in total economic output, which the CRN Economic Study calculates to be roughly 0.68 percent of the United States' gross domestic product. The Study also reports the industry directly employed 383,230 Americans in 2016 with collective earnings of over \$16 billion in wages and benefits. According to the Study, extrapolation to include indirect and induced impacts of the dietary supplement industry provides an estimate of 754,645 U.S. jobs and \$38.36 billion in wages, and total Federal, state and local wage and business related taxes (exclusive of state and local sales taxes on supplements where those are collected) of \$14.94 billion.

#### The U.S. dietary supplement industry consists mainly of small businesses

In considering the possible impact of the Proposed Product List on U.S. dietary supplement companies it is important to recognize that a significant portion of these companies are small businesses.

The U.S. Food and Drug Administration (FDA or the Agency) in June 2007 issued a final rule on Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (the cGMP final rule), now codified at Title 21 of the Code of Federal Regulations, Part 111 (21 C.F.R. 111). In promulgating this rule, FDA examined its economic implications, as required by the

<sup>&</sup>lt;sup>7</sup> John Dunham & Associates. June 2016. Economic Impact of the Dietary Supplement Industry. Data accessed on June 17, 2019 at <u>http://www.crnusa.org/resources/economic-impact-dietary-supplement-industry</u>. Information on the methodology and documentation for preparation of these data was accessible at <u>http://nutrition.guerrillaeconomics.net/assets/site/res/CRN%20Methodology.pdf</u> as of June 17, 2019.

Regulatory Flexibility Act, and in so doing found that the final rule would have "a significant economic impact on a substantial number of small entities."<sup>8</sup>

FDA estimated at that time that there were 1,460 establishments that manufacture, package, label, or distribute<sup>9</sup> dietary supplement products in the United States and that would be subject to 21 C.F.R. 111, as would an additional 15,869 "general warehouses, wholesalers, and other" firms in the U.S. that "hold dietary supplements, but are not otherwise involved in the industry."<sup>10</sup> FDA also noted that it did not have data on the number of foreign firms that export dietary supplements to the United States, but observed that data available in the Agency's dietary supplement sales database suggested that relatively few foreign firms export dietary supplements to the United States.<sup>11</sup> It can be assumed then that most dietary supplement products marketed in the U.S. are also made in the U.S. by companies that provide U.S. jobs.

The Agency went on in the 2007 final cGMP rulemaking to calculate that 1,300 (i.e., 89 percent) of the 1,460 U.S. manufacturers, packagers, labelers, or distributors of dietary supplement products who are subject to 21 C.F.R. 111 were small entities with fewer than 500 employees, including 774 firms (i.e., 53 percent) that would be classified as very small entities with fewer than 20 employees. FDA also estimated that 15,421 (i.e., 97 percent) of the additional 15,869 distributors of dietary supplements that it had described as "general warehouses, wholesalers, and others that hold dietary supplements, but are not otherwise involved in the industry" were also small businesses.<sup>12</sup>

In addition to the companies identified in the previous paragraph, FDA also estimated in the cGMP final rule in 2007 that there were an additional 106 U.S. establishments that supplied dietary ingredients (as opposed to finished dietary supplement

<sup>11</sup> Ibid.

<sup>&</sup>lt;sup>8</sup> 72 FR 34751 at 34938.

<sup>&</sup>lt;sup>9</sup> FDA uses the words "hold" and "holder" to indicate activities and firms that must comply with the "holding operations" elements of 21 C.F.R. 111. AHPA believes the words "distribute" and "distributor" are more readily understood and so has substituted these words in these comments.

<sup>&</sup>lt;sup>10</sup> 72 FR 34751 at 34920.

<sup>&</sup>lt;sup>12</sup> 72 FR 34751 at 34938.

products) at the time;<sup>13</sup> the Agency did not include these firms in its analysis as they were not subject to the cGMP final rule. It should be noted, however, that these U.S. dietary ingredient suppliers will also be directly impacted by the Proposed Product List if they import any of the ingredients included in the HTSUS codes listed therein, and so they too will need to absorb or pass on to their customers the additional 25 percent *ad valorem* duty proposed for any ingredients in the many HTSUS subheadings included in this USTR proposal. It is reasonable to assume that the same high proportion of these firms are also small businesses.

The numbers of each of the types of businesses in the dietary supplement industry discussed above have increased since 2007. For example, FDA in August 2015 estimated there to be 1,700 dietary supplement companies subject to a separate regulation, and explained that its revision had been calculated by "using the figure 1,460 as provided in our final rule of June 25, 2007 (72 FR 34751), on the 'Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,' and factoring for a 2 percent annual growth rate."<sup>14</sup> The Agency did not at that time provide any update on its estimate of the number of such firms that are small or very small entities. Nor did FDA provide in this 2015 document a revised estimate of the number of distributors of dietary supplements, but are not otherwise involved in the industry."

AHPA has calculated additional extrapolations to estimate, as of 2019, the number of small businesses in the several sectors of the dietary supplement industry that have been described here that stand to be negatively affected by inclusion of the HTSUS subheadings relevant to this industry that are included in the Annex in the Proposed Product List. Based on FDA's estimate of a 2 percent annual increase in the number of such companies and assuming the same proportion in each category would still be classified as small businesses, AHPA projects that as of 2019 there are approximately:

- 1,649 small entities who are U.S. manufacturers, packagers, labelers, or distributors of dietary supplements, subject to 21 C.F.R. 111;
- 120 small entities who are U.S dietary ingredient suppliers; and

<sup>13 72</sup> FR 34751 at 34920.

<sup>&</sup>lt;sup>14</sup> 80 FR 51278 at 51280.

• 19,558 small entities who are other U.S. distributors of dietary supplements.

It should therefore be obvious, based on data provided by FDA, that any financial harm or job loss to the dietary supplement industry that may be caused by the Proposed Product List will be borne primarily by small U.S. businesses that provide U.S. jobs, and that tens of thousands of companies will be affected.

Of additional concern is that many of AHPA's members also manufacture and market herbal products that are sold in categories other than dietary supplements, such as teas and other foods, cosmetics, household items, etc. An additional 25 percent *ad valorem* duty on Chinese-sourced ingredients will increase costs and potentially result in marketplace disruptions for these other herbal products. USTR should therefore also consider the financial implications and added burdens of the Proposed Product List on the U.S. manufacturers and marketers, as well as U.S. consumers, of these products.

#### Estimates of potential costs

Several AHPA member companies provided estimates, ranging from several hundred thousand dollars to as much as \$2.4 million, of their individual company's increased annual costs that would result from an additional 25 percent *ad valorem* duty on those ingredients from China used in their dietary supplement and other herbal products identified in the prior list of subject tariff subheadings – i.e., the Proposed Supplemental Trade Action as issued in USTR's Federal Register notice issued in the July 17 Notice on July 17, 2018. AHPA has not yet obtained similar financial data for the additional tariff subheadings included in the Proposed Product List in the Annex to the May 17 Notice, but certainly the potential costs of the proposed modification will be additive to these earlier estimates.

Given that the majority of companies in the U.S. dietary supplement industry are privately held, AHPA does not have sufficient marketplace data to extrapolate these limited individual company reports to the industry as a whole. It is reasonable to assume, however, that the cumulative increased costs for Chinese-source ingredients that would be borne by U.S. manufacturers and marketers of these products would be tens of millions of dollars annually if the U.S. imposes an additional 25 percent *ad valorem* duty on goods from China in all of the HTSUS subheadings identified in the Proposed Product List that include materials used in these products.

#### Replacing current supply chains requires significant time and resources

Manufacturers of finished consumer goods in any product category rely on consistent ingredient supplies and a stable supply chain. This may be particularly true today for manufacturers of foods, including dietary supplements and other herbal food products, such as herbal teas, due to regulations newly promulgated over the last several years to implement the Food Safety Modernization Act signed into law in early 2011.

As noted elsewhere in these comments, many ingredients used in dietary supplements and other herbal products are imported from China for use by U.S. manufacturers and marketers of these products, and for many such ingredients China is the primary or only source. These include cultivated crops that are used to produce commodities included in the Proposed Product List and used in U.S. manufactured herbal products. Farmers in alternate countries might eventually be enticed to cultivate these crops, but for some of these it will be years before the article in trade is ready to harvest. These include a wide variety of herbal crops such as roots, bark, leaves, flowers, fruit, seeds, etc., many of which can require anywhere from three years to over a decade before the plants are sufficiently mature to harvest the crop.

Even if suppliers in other countries decide to cultivate or produce crops currently sourced from China, in many cases the resulting material may not meet the needs of U.S. companies. By law, ingredients used in dietary supplements must meet stringent manufacturer-set specifications for freedom from contaminants that may adulterate the finished product, and manufacturers of these and other herbal products often set composition specifications such as on the content of various botanical constituents. These variables can be significantly impacted by growing and cultivation conditions.

Finally, even if manufacturers can locate material from alternate countries that meets the necessary specifications, it is not easy or inexpensive for U.S. companies to switch to new foreign vendors. U.S. companies are required to ensure the safety and quality of the ingredients they import and must comply with the burdens of FDA's Foreign Supplier Verification Program regulations (21 C.F.R. Part 1 Subpart L). Furthermore, they must ensure, among other things, that foreign growers comply with applicable requirements of the Produce Safety regulations (21 C.F.R. Part 112); that foreign processors comply with FDA food facility registration requirements; and that foreign processors comply with the applicable Good Manufacturing Practice regulations for food (21 C.F.R. Part 117 and/or Part 111, among others). There are also regulations pertaining to the safe transportation of food (21 C.F.R. Part 1 Subpart O) and preventing intentional adulteration (21 C.F.R. Part 121) to be considered. Complying with FDA requirements to evaluate the quality, suitability, and regulatory compliance of new potential ingredient sources is a complex, time-intensive, and expensive process.

In sum, it will be difficult, costly, and time-consuming for companies to identify appropriate ingredient sources outside China in order to avoid any additional *ad valorem* duties; and, in many cases, such alternate sources do not exist and cannot quickly be created.

#### Harm to U.S. businesses

It is obvious that increased costs for ingredients used in dietary supplements would necessarily lead U.S. companies that manufacture and market these products in the United States and internationally to either increase the retail costs of these goods, sell them to consumers with lower profit margins, or in some cases discontinue products that become too expensive. None of these options is an ideal business decision for such companies, and each of these options will potentially put U.S. jobs and business growth in this sector at risk.

For example, if companies facing an additional 25 percent *ad valorem* duty on key ingredients increase their retail pricing commensurately at the same 25 percent rate, they run the risk of losing sales and customers, which could lead to job loss, or reduced business growth, or even worse outcomes such as outright business closures. Accurate determination of price elasticity is complex, but a meta-analysis of 81 published studies determined an average price elasticity of -2.62 for sales to consumers;<sup>15</sup> on this basis, a 25 percent price increase corresponds to a 66 percent decrease in the quantity of product sold. This would be a catastrophic result for any business. Even if dietary supplements and other herbal products more closely reflect the lower price elasticity of foods such as beef or juice (which seems unlikely, given that purchases of these products are discretionary compared to conventional foods, and therefore should exhibit higher price elasticity), a 25 percent price increase would

<sup>&</sup>lt;sup>15</sup> Bijmolt THA, van Heerde HJ, and Pieters RGM. May 2005. New empirical generalizations on the determinants of price elasticity. *J Marketing Res* 42(2):141-156.

still correlate to approximately a 19 percent reduction in sales volume.<sup>16</sup> This is still a very large drop in sales that will still cause severe difficulties for the affected businesses.

Thus companies faced with a 25 percent increase in ingredient prices will be forced either to adjust to drastically reduced sales volumes (if the price increase is largely passed along to consumers or products are discontinued entirely), drastically reduced margins (if the price increase is largely absorbed by the company), or some combination of both, any of which will significantly reduce companies' profitability. AHPA furthermore notes that dietary supplement companies often do not enjoy margins large enough to absorb significant price increases; many firms operate on net margins of less than 10 percent. Thus, the proposed tariff increases of 25 percent will inevitably lead to reduced profitability, job losses, and even outright business failures.

In addition, U.S. companies that manufacture concentrated extracts will be placed at a particular economic disadvantage due to the multiplier effects of extract ratios. Many extracts serve to concentrate the original starting material; for example, in a 4:1 extract each 1 pound of finished extract corresponds to 4 pounds of raw material. In such cases, every \$1 increase in raw material costs will translate into a \$4 increase in the finished extract cost. Such large cost increases will be severely deleterious to the affected companies.

#### Harm to American consumers

Described above are various possible responses by U.S. manufacturers and marketers of dietary supplements and other herbal products in the face of ingredient cost increases from the possible additional 25 percent *ad valorem* duty on ingredients in HTSUS subheadings included in the Proposed Product List used in these products. Again, these companies will be forced to either increase retail prices or reduce profit margins on products impacted by the proposed duty, or they may decide to eliminate affected products entirely.

<sup>&</sup>lt;sup>16</sup> Researchers have estimated the absolute value of the price elasticity of beef to be 0.75 and juice 0.76. See Andreyeva T, Long MW, and Brownell KD. February 2010. The impact of food prices on consumption: A systematic review of research on the price elasticity of demand for food. *Am J Public Health* 100(2):216-222.

In any of the above scenarios consumers of these products will also be harmed by inclusion of the identified HTSUS subheadings in the Proposed Product List, as American consumers may either have to pay higher prices for these goods or find the products they seek to be unavailable.

Recent estimates of the portion of the U.S. adult population that use dietary supplements range from 52 percent<sup>17</sup> to 76 percent.<sup>18</sup> Analyses have also been conducted on various American subpopulations, and reports have found supplement use by 33 percent of children and adolescents,<sup>19</sup> 66 percent of college students,<sup>20</sup> and 70 percent of Americans over 60 years of age.<sup>21</sup> As recently noted by Dr. Scott Gottlieb, former Commissioner of Food and Drugs,<sup>22</sup> dietary supplements "play an important role in our lives as we strive to stay healthy" and can have particular benefits as part of U.S. consumers' comprehensive care plans.

Thus any increase in costs or reduction in choices or availability of dietary supplements would affect many million American consumers, and would have negative impacts in all U.S. age categories. While AHPA does not have similar data on Americans' use of other herbal products, such as teas or cosmetics, certainly any marketplace disruptions to these products would also affect many U.S. consumers.

In light of dietary supplements' important role in promoting the health of the U.S. population, USTR should exclude from any final version of the Proposed Product List ingredients used in these products. This would appear consistent with USTR's

<sup>19</sup> Qato DM *et al.* June 2018. Prevalence of dietary supplement use in US children and adolescents, 2003-2014. *JAMA Pediatrics* doi:10.1001/jamapediatrics.2018.1008.

<sup>20</sup> Lieberman HR *et al.* October 2015. Patterns of dietary supplement use among college students. *Clinical Nutrition* 34:976-985.

<sup>21</sup> Gahche JJ *et al.* October 2017. Dietary supplement use was very high among older adults in the United States in 2011–2014. *J Nutrition* 147(10):1968-1976.

<sup>22</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight, <u>https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary</u> (Feb. 11, 2019).

<sup>&</sup>lt;sup>17</sup> Kantor ED *et al.* October 2016. Trends in dietary supplement use among US adults from 1999-2012. *JAMA* 316(14):1464-1474.

<sup>&</sup>lt;sup>18</sup> CRN 2017 Annual Survey on Dietary Supplements; accessed on June 17, 2019 at <u>https://www.crnusa.org/resources/crn-2017-annual-survey-dietary-supplements</u>.

justified decision, as stated in the May 17 Notice, to exclude "pharmaceuticals, certain pharmaceutical inputs, [and] select medical goods" from the scope of the proposed action. AHPA recognizes that dietary supplements serve a different function (i.e., promoting and maintaining health) than pharmaceuticals (i.e., curing, treating, or mitigating disease), but both categories of goods play important roles in the health of U.S. consumers. Food in general is also essential to human health and USTR should therefore also consider removing from the Proposed Product List all food ingredients. Imposing higher food costs, as will be inevitable if USTR retains a 25 percent *ad valorem* tariff on food ingredients exported from China, will disproportionately impact lower income Americans and will increase expenses for governmental and non-profit entities charged with ensuring food security for the U.S. population.

#### <u>Harming U.S. businesses and American consumers is inconsistent with USTR's own</u> <u>criteria for selecting appropriate Chinese exports for imposition of duties</u> As noted at the outset of these comments, USTR has reported on the criteria used by the trade analysts engaged in the process of determining the specific goods exported

by China on which additional *ad valorem* duties should be imposed as a U.S. response to the Section 301 Investigation. USTR has consistently stated that these criteria have included attention to minimizing impacts on the U.S. economy and on U.S. consumers.

For example, in the April 6 Notice issued on April 6, 2018, USTR reported that the trade analysts who identified the products for listing in the Initial Trade Action described in that notice refrained from including specific products identified by the analysts as "likely to cause disruptions to the U.S. economy" and that they selected products for inclusion in this Action from those "with lowest consumer impact."<sup>23</sup> Similarly, in the June 20 Notice issued on June 20, 2018, USTR reported its responsiveness to comments submitted in relation to the Initial Trade Action that expressed concern "that imposition of additional duties on the specific products would cause severe economic harm to a U.S. interest...."<sup>24</sup> And USTR also noted in the July 17 Notice issued on July 17, 2018 that the list of HTSUS subheadings included in the Proposed Supplemental Trade Action described in that action was developed

<sup>23 83</sup> FR 14906 at 14907.

<sup>&</sup>lt;sup>24</sup> 83 FR 28710 at 28711.

with attention to "likely impacts on U.S. consumers," and that HTSUS subheadings identified by analysts as "likely to cause disruptions to the U.S. economy" were removed from this most recent list.<sup>25</sup> Also, in its requests for comments to the April 6 Notice, the June 20 Notice, and the July 17 Notice, and also in the May 17 Notice that is the immediate subject of these comments, USTR specifically requested that commenters address whether imposing additional duties on products in the subheadings proposed in these Notices would cause disproportionate economic harm to U.S. interests, including small or medium-sized businesses.<sup>26</sup>

It is thus AHPA's strong view that no matter how well intentioned USTR has been in the process of developing the Proposed Product List to minimize impacts on U.S. consumers and harm to the U.S. economy, and by extension, to the businesses that make up the U.S. economy, inclusion of the HTSUS subheadings that cover many ingredients used in dietary supplements and other herbal products manufactured and marketed in the United States will inevitably harm both American citizens and U.S. businesses, especially small businesses in the dietary supplement and natural products industry. In AHPA's view, such effects would be inconsistent with the Congressional intent of the Trade Act, which purposes include, in relevant part to these comments, "to foster the economic growth of and full employment in the United States…"<sup>27</sup> and "…to assist industries, firm[s], workers, and communities to adjust to changes in international trade flows."<sup>28</sup>

### **Concluding statement**

AHPA is requesting by these comments that USTR remove from the Proposed Product List and exclude from any resultant final list all of the HTSUS subheadings listed in the Annex in the May 17 Notice that are identified in these comments as relevant to ingredients used in dietary supplements and other herbal products manufactured or marketed in the United States. AHPA is also requesting that consideration be given to excluding from any final version of the Proposed Product

<sup>25 83</sup> FR 33608 at 33610.

<sup>&</sup>lt;sup>26</sup> 83 FR 14906 at 14908; 83 FR 28710 at 28712; and 83 FR 33608 at 33609.

<sup>&</sup>lt;sup>27</sup> 19 U.S.C. 2102(1).

<sup>&</sup>lt;sup>28</sup> 19 U.S.C. 2102(4).

List ingredients used in dietary supplement and general food products as these play important roles in the health of U.S. consumers.

As described in detail above, AHPA has significant concerns regarding likely negative effects on U.S. businesses, especially small businesses, and American consumers from imposition of an additional 25 percent *ad valorem* duty on the many items included in the HTSUS subheadings in the Proposed Product List as listed in the Annex in the May 17 Notice that are identified in these comments as relevant to U.S. manufacturers and marketers of dietary supplements and other herbal products. Any such harm would be inconsistent with the criteria USTR has described as the basis for the selection of the HTSUS subheadings to which additional *ad valorem* duty should be imposed on Chinese exports.

AHPA appreciates the opportunity to present comments on this process and welcomes any questions that may arise from AHPA's comments.

Respectfully submitted,

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