

Docket No. USTR–2018–0026

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**

September 6, 2018

Table of Contents

Prefatory remarks	1
<i>Overview and summary of points</i>	6
The Proposed Supplemental Trade Action will harm U.S. businesses and American consumers.....	7
The HTSUS subheadings relevant to the dietary supplements and herbal products industries are not relevant to China’s “Made in China 2025” policy	20
AHPA requests removal of HTSUS subheadings relevant to the dietary supplements and herbal products industries from the Proposed Supplemental Trade Action.....	21
Concluding statement	24

Prefatory remarks

On April 6, 2018 the Office of the United States Trade Representative (USTR or the Trade Representative) published a Federal Register notice (the April 6 Notice¹) in which the Trade Representative communicated its determination, based on an investigation under section 301 (the section 301 investigation) of the Trade Act of 1974 (the Trade Act), that the acts, policies, and practices of the Government of China related to technology transfer, intellectual property, and innovation covered in the investigation are unreasonable or discriminatory and burden or restrict U.S. commerce.

In the April 6 Notice USTR also proposed and requested public comments on imposition of an additional *ad valorem* duty² of 25 percent on a list of certain products from China set out in an Annex to the April 6 Notice (the Initial Trade Action). The Initial Trade Action identified products from China classified in a list of 1,333 tariff subheadings of the Harmonized Tariff Schedule of the United States (HTSUS) estimated to have a value of \$50 billion in terms of annual trade value for calendar year 2018.³ In its request for comments, USTR specifically requested that commenters address, among other things, whether imposing increased duties on a particular HTSUS subheadings identified in the Annex in that Notice would cause disproportionate economic harm to U.S. interests, including small or medium-sized businesses and consumers.⁴

In the April 6 Notice USTR also provided an explanation for how the list of specific HTSUS subheadings included in the proposed Initial Trade Action was developed, and stated the following methodology was used:

¹ 83 FR 14906.

² In the April 6 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.

³ 83 FR 14906 at 14907.

⁴ 83 FR 14906 at 14908.

“Trade analysts from several U.S. Government agencies identified products that benefit from Chinese industrial policies, including Made in China 2025. The list was refined by removing 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. The remaining products were ranked according to the likely impact on U.S. consumers, based on available trade data involving alternative country sources for each product. The proposed list was then compiled by selecting products from the ranked list with lowest consumer impact.”⁵

USTR subsequently published a related Federal Register notice on June 20, 2018 (the June 20 Notice⁶) in which the Trade Representative announced that, based on a review of comments submitted in response to the April 6 Notice, it had determined to narrow the proposed list of products from China identified in the Initial Trade Action to 818 HTSUS tariff subheadings, listed in Annex A and in Annex B (with unofficial descriptions of the types of products covered in each subheading) of that Notice, with an approximate annual trade value of \$34 billion.

The June 20 Notice also identified and requested comment on 284 additional proposed tariff subheadings, listed in Annex C of that Notice, with an estimated annual trade value of \$16 billion that would be appropriate for action in the form of imposition of an additional 25 percent *ad valorem* duty (the Additional Trade Action). In making this request for comments, USTR again specifically requested that commenters address, among other things, whether imposing increased duties on a particular HTSUS subheadings identified in Annex C in the Notice would cause disproportionate economic harm to U.S. interests, including small or medium-sized businesses and consumers.⁷

In the June 20 Notice, USTR also reported that during the notice and comment process in relation to the April 6 Notice and the Initial Trade Action:

“...a number of interested persons asserted that specific products within a particular tariff subheading were only available from China, that imposition of additional duties on the specific products would cause severe economic harm to a

⁵ 83 FR 14906 at 14907.

⁶ 83 FR 28710.

⁷ 83 FR 28710 at 28712.

U.S. interest, and that the specific products were not strategically important or related to the ‘Made in China 2025’ program.”⁸

USTR therefore stated its intention, in light of these concerns and pursuant to several specified sections of the Trade Act to:

“...establish a process by which U.S. stakeholders may request that particular products classified within an HTSUS subheading listed in Annex A be excluded from these additional duties. USTR will publish a separate notice describing the product exclusion process, including the procedures for submitting exclusion requests, and an opportunity for interested persons to submit oppositions to a request.”⁹

In relation to this statement of its intention to establish a process for requesting exclusion from additional duties of products within an HTSUS subheading listed in Annex A of the June 20 Notice as subject to an additional tariff in the matter of the section 301 investigation, USTR subsequently published a Federal Register notice on July 11, 2018 (the Exclusions Process Notice) in which it set out the specific procedures and criteria related to requests for Annex A product exclusions; reported it had opened up a docket for the receipt of exclusion requests; and stated that USTR must receive requests to exclude a particular product listed in Annex A by October 9, 2018.¹⁰

On July 17, 2018 the USTR published another related Federal Register notice (the July 17 Notice¹¹) in which the Trade Representative proposed and requested public comments on a modification to the earlier actions taken by the United States in response to the section 301 investigation. In the July 17 Notice the Trade

⁸ 83 FR 28710 at 28711.

⁹ Ibid.

¹⁰ 83 FR 32181 at 32182. The Exclusions Process Notice stated its relevance to duties of “a particular product classified within a HTSUS subheading set out in Annex A of the notice published at 83 FR 28710 (June 20, 2018).” This Annex A lists just the 818 HTSUS subheadings that were included in the Initial Trade Action issued in the April 6 Notice and retained after USTR’s review of comments to this initial list. Thus it appears that USTR has not to date set out procedures and criteria to allow for requests for exclusion of any of the 284 HTSUS subheadings listed in Annex C of the June 20 Notice or of the 6,031 subheadings listed in the Annex issued subsequently in the July 17 Notice.

¹¹ 83 FR 33608.

Representative identified and requested comments on a proposal to take further action in this matter in the form of an additional 10 percent *ad valorem* duty on products of China in 6,031 HTSUS subheadings, listed in an Annex in this Notice, with an annual trade value of approximately \$200 billion (the Proposed Supplemental Trade Action).

Much as it had in the April 6 Notice, USTR provided in the July 17 Notice some explanation for how the list of HTSUS subheadings included in the Proposed Supplemental Trade Action was developed, as follows:

“In developing the list of tariff subheadings included in this proposed supplemental action, trade analysts considered products from across all sectors of the Chinese economy. The tariff subheadings considered by the analysts included subheadings that commenters suggested for inclusion in response to the April 6 notice. 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.”¹²

In addition, and much as it had in the June 20 Notice, in requesting comments on the new list of HTSUS subheadings identified in the July 17 Notice, USTR specifically requested that commenters address, among other things, whether imposing increased duties on a particular HTSUS subheading identified in the Annex in the Notice would cause disproportionate economic harm to U.S. interests, including small or medium-sized businesses and consumers.¹³

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 harm to U.S. business or consumer interest. AHPA views this attention 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...”¹⁴ and

¹² 83 FR 33608 at 33610.

¹³ 83 FR 33608 at 33609.

¹⁴ 19 U.S.C. 2102(1).

“...to assist industries, firm, workers, and communities to adjust to changes in international trade flows.”¹⁵

In a revision to the Proposed Supplemental Trade Action as initially issued in the July 17 Notice, USTR issued a Federal Register notice on August 7 (the August 7 Notice¹⁶) that reported that the President had directed the Trade Representative to consider raising the level of the additional duty in this action from 10 percent to 25 percent. The August 7 Notice therefore requested comments on the possible imposition of an additional 25 percent *ad valorem* duty on the 6,031 HTSUS subheadings identified in the Proposed Supplemental Trade Action as listed in the Annex in the July 17 Notice.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of 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 the United States and in other countries as foods, food or dietary supplements, drugs, cosmetics, and other product categories. 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 and are specifically in response to the Proposed Supplemental Trade Action as initially identified in the July 17 Notice and as amended in the August 7 Notice, such that these comments assume imposition of an additional 25 percent *ad valorem* tariff on each of the goods in any HTSUS subheading identified in the Proposed Supplemental Trade Action as listed in the Annex in the July 17 Notice.

Note however that AHPA is not offering comments to all elements of the Proposed Supplemental Trade Action; absence of comments on any element or section of this

¹⁵ 19 U.S.C. 2102(4).

¹⁶ 83 FR 38760.

proposal in the July 17 Notice or the August 7 Notice should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated.

Overview and summary of points

AHPA is requesting in these comments that USTR and the Trade Representative remove from the Proposed Supplemental Trade Action all of the HTSUS subheadings listed in the Annex in the July 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 Proposed Supplemental Trade Action. 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, workers, and communities to adjust to changes in international trade flows.” In AHPA’s view, the effects of this Trade Action on U.S. businesses and American consumers would be inconsistent with the intent of Congress in passing the Trade Act.

AHPA has provided significant information in support of this request, including:

- The Proposed Supplemental Trade Action 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 by individual U.S. manufacturers and marketers of dietary supplements and other herbal products of the costs they will bear from the proposed 25 percent *ad valorem* duty on the HTSUS subheadings identified in these comments are reported to be as much as \$2.4 million for individual companies;
- U.S. manufacturers and marketers of these 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 Supplemental Trade Action will cause significant disruptions to occur in ingredient supply chains, which will require significant resources and unacceptable time lapses to address;
- A significant portion of the American population use dietary supplements and other herbal products, and these consumers will encounter increased prices or reduced selection, or both, if USTR goes forward with this Action as proposed;
- Imposition of an additional 25 percent *ad valorem* duty on goods in the HTSUS subheadings identified in these comments will have no impact of China's Made in China 2025 policy;
- 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 Supplemental Trade Action.

The Proposed Supplemental Trade Action will harm U.S. businesses and American consumers

The Proposed Supplemental Trade Action as published in the July 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, etc. 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 list of HTSUS subheadings listed in the Proposed Supplemental Trade Action in the Annex to the July 17 Notice that identify ingredients of concern to AHPA's members include but may not be limited to the following:

- 0404.10.05: Whey protein concentrates
- 0712.20.20: Dried onion powder or flour
- 0712.20.40: Dried onions whole, cut, sliced or broken, but not further prepared
- 0712.31.10: Air dried or sun dried mushrooms of the genus *Agaricus*, whole, cut, sliced, broken or in powder, but not further prepared
- 0712.31.20: Dried (not air or sun dried) mushrooms of the genus *Agaricus*, whole, cut, sliced, broken or in powder, but not further prepared
- 0712.32.00: Dried wood ears (*Auricularia* spp.), whole, cut, sliced, broken or in powder, but not further prepared
- 0712.33.00: Dried jelly fungi (*Tremella* spp), whole, cut, sliced, broken or in powder, but not further prepared
- 0712.39.10: Air dried or sun dried mushrooms (other than of the genus *Agaricus*), whole, cut, sliced, broken or in powder, but not further prepared
- 0712.39.20: Dried (not air or sun dried) mushrooms (other than of the genus *Agaricus*), whole, cut, sliced, broken or in powder, but not further prepared
- 0712.39.40: Dried truffles, whole, cut, sliced, broken or in powder, but not further prepared
- 0712.90.10: Dried carrots, whole, cut, sliced, broken or in powder, but not further prepared
- 0712.90.40: Dried garlic, whole, cut, sliced, broken or in powder, but not further prepared
- 0712.90.60: Dried fennel, marjoram, parsley, savory and tarragon, crude or not manufactured
- 0712.90.65: Dried parsley nesoi, whole, cut, sliced, broken or in powder, but not further prepared
- 0712.90.70: Dried fennel, marjoram, savory and tarragon nesoi, whole, cut, sliced, broken or in powder, but not further prepared
- 0712.90.74: Tomatoes, dried in powder
- 0712.90.78: Tomatoes, dried, whole, other
- 0712.90.85: Dried vegetables nesoi, and mixtures of dried vegetables, whole, cut, sliced, broken or in powder, but not further prepared
- 1714.90.61: Dried dasheens, arrowroot, salep, Jerusalem artichokes, and similar roots and tubers nesoi, whether or not sliced but not in pellets

- 0801.11.00: Coconuts, desiccated
- 0802.80.20: Areca nuts, fresh or dried, shelled
- 0804.50.80: Guavas, mangoes, and mangosteens, dried
- 0813.30.00: Apples, dried
- 0813.40.10: Papayas, dried
- 0813.40.13: Barberries, dried
- 0813.40.20: Berries except barberries, dried
- 0813.40.30: Cherries, dried
- 0813.40.40: Peaches, dried
- 0814.00.10: Peel of orange or citron, fresh, frozen, dried or provisionally preserved in brine, in sulfur water or other preservative solutions
- 0814.00.80: Peel of citrus fruit, excl. orange or citron and peel, nesoi, of melon, fresh, frozen, dried or provisionally preserved
- 1204.00.00: Flaxseed (linseed), whether or not broken
- 1206.00.00: Sunflower seeds, whether or not broken
- 1207.40.00: Sesame seeds, whether or not broken
- 1207.50.00: Mustard seeds, whether or not broken
- 1207.91.00: Poppy seeds, whether or not broken
- 1207.99.03: Other oil seeds and oleaginous fruits whether or not broken, incl niger seeds, hemp seeds and seeds nesoi
- 1211.20.10: Ginseng roots, fresh or dried, whether or not cut, crushed or powdered
- 1211.90.20: Mint leaves, crude or not manufactured, of a kind used in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes
- 1211.90.40: Mint leaves nesoi, of a kind used in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes
- 1211.90.92: Plants, parts of plants (including seeds and fruits), used in perfumery, pharmacy, insecticidal, fungicidal or similar purposes, other, fresh or dried
- 1212.21.00: Seaweeds and other algae, fresh, chilled, frozen or dried, whether or not ground, fit for human consumption
- 1212.29.00: Seaweeds and other algae, fresh, chilled, frozen or dried, whether or not ground, other than for human consumption
- 1212.92.00: Locust beans (carob)
- 1212.99.30: Apricot, peach (other than nectarine) or plum stones and kernels used primarily for human consumption, not elsewhere specified or included
- 1504.10.20: Cod liver oil and its fractions

- 1504.10.40: Fish-liver oils and their fractions, other than cod-liver oil and its fractions
- 1504.20.20: Cod oil and its fractions, other than liver oil
- 2510.10.00: Natural calcium phosphates, natural aluminum calcium phosphates and phosphatic chalk, unground
- 2510.20.00: Natural calcium phosphates, natural aluminum calcium phosphates and phosphatic chalk, ground
- 2805.12.00: Calcium
- 2827.20.00: Calcium chloride
- 2827.60.20: Iodide and iodide oxide of potassium
- 2835.26.00: Other phosphates of calcium, nesoi
- 2836.50.00: Calcium carbonate
- 2918.15.50: Salts and esters of citric acid
- 2918.16.50: Salts and esters of gluconic acid
- 3104.20.00: Potassium chloride

In addition, several HTSUS subheadings listed in the Proposed Supplemental Trade Action in the Annex in the July 17 Notice are for packaging materials; those of concern to AHPA's members include but may not be limited to the following:

- 3923.30.00: Carboys, bottles, flasks and similar articles for the conveyance or packing of goods, of plastics
- 3923.50.00: Stoppers, lids, caps and other closures, of plastics
- 3923.90.00: Articles nesoi, for the conveyance or packing of goods, of plastics
- 7010.90.20: Glass containers for conveyance/packing perfume/toilet preps & containers with/ designed for ground glass stopper, made by automatic machine
- 7010.90.50: Glass carboys, bottles, jars, pots, flasks, & other containers for conveyance/packing of goods (w/wo closures) & preserving jars, nesoi

AHPA has consulted with several of its members who use ingredients and packaging components imported from China in their dietary supplements and other herbal products marketed in the United States to American consumers, including items in one or more of the above listed HTSUS subheadings. Many of the finished products marketed in the U.S. and using these materials are also manufactured in the U.S., such that manufacturers of these products provide U.S. jobs.

The dietary supplement industry provides U.S. jobs

Data on the economic impact of the dietary supplement industry in the U.S. was published in 2016 on behalf of the Council for Responsible Nutrition (the CRN Economic Study), a trade association that represents the dietary supplement industry.¹⁷ 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, who collectively earned over \$16 billion in wages and benefits. According to the CRN Economic 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 Supplemental Trade Action 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 CFR 111). In promulgating this rule, FDA examined its economic implications, as required by the 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.”¹⁸

¹⁷ John Dunham & Associates. June 2016. Economic Impact of the Dietary Supplement Industry. Data accessed on September 2, 2018 at <http://www.crnusa.org/resources/economic-impact-dietary-supplement-industry>. Information on the methodology and documentation for preparation of this data was accessible at <http://nutrition.guerrillaeconomics.net/assets/site/res/CRN%20Methodology.pdf> as of September 2, 2018.

¹⁸ 72 FR 34751 at 34938.

FDA estimated at that time that there were 1,460 establishments that manufacture, package, label, or distribute¹⁹ dietary supplement products in the United States that would be subject to 21 CFR 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.”²⁰ 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.²¹ 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 CFR 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.²²

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 products) at the time;²³ 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

¹⁹ FDA uses the words “hold” and “holder” to indicate activities and firms that must comply with the “holding operations” elements of 21 CFR 111. AHPA believes the words “distribute” and “distributor” are more readily understood and so has substituted these words in these comments.

²⁰ 72 FR 34751 at 34920.

²¹ *Ibid.*

²² 72 FR 34751 at 34938.

²³ 72 FR 34751 at 34920.

Supplemental Trade Action 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.”²⁴ 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 that it had described in 2007 as “general warehouses, wholesalers, and others” that “hold 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 Supplemental Trade Action. 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 will be approximately:

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

²⁴ 80 FR 51278 at 51280.

Proposed Supplemental Trade Action 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. The financial impact of a possible additional 25 percent *ad valorem* duty on Chinese-sourced ingredients on the increased costs and possible marketplace disruptions for these other herbal products should therefore also be considered, and the possible financial implications of the Proposed Supplemental Trade Action will very likely be to increase burdens on U.S. manufacturers and marketers, as well as U.S. consumers, of these products.

Estimates of potential costs

Several AHPA's member companies have provided estimates of their individual company's increased annual costs, ranging from several hundred thousand dollars to as much as \$2.4 million, if the U.S. imposes an additional 25 percent *ad valorem* duty on ingredients from China used in their dietary supplement and other herbal products and identified in the Proposed Supplemental Trade Action in the Annex to the July 17 Notice. Given that the majority of companies in the U.S. 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 Supplemental Trade Action 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. For example, the herbal ingredient eleuthero (*Eleutherococcus senticosus*) root used to be available from multiple countries, but as prices have dropped suppliers in most countries have discontinued production of this crop, leaving China as the only viable source. Farmers in alternate countries might eventually be enticed to cultivate eleuthero root, but even then it will be years before the roots are ready to harvest. The same is true for a wide variety of dietary ingredient crops which consist of 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. Ingredients used in dietary supplements must meet stringent regulatory specifications for freedom from contaminants that may adulterate the finished product, and manufacturers of these and other herbal products often set composition specification such as on the content of various botanical constituents. These variables can be significantly impacted by growing and cultivation conditions.

Finally, even if material from alternate countries can be located which meets the necessary specifications, it is not easy or cheap 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 CFR Part 1 Subpart L). Furthermore, they must ensure any foreign growers comply with applicable requirements of the Produce Safety regulations (21 CFR 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 CFR Part 117 and/or Part 111, among others). There are also regulations pertaining to the safe transportation of food (21 CFR Part 1 Subpart O) and preventing intentional adulteration (21 CFR Part 121) to be considered. To fully evaluate the quality, suitability, and regulatory compliance of new potential ingredient sources is a complex 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 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;²⁵ on this basis, a 25 percent price increase corresponds to a 66% 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 still correlate to approximately a 19 percent reduction in sales volume.²⁶ This is still a very large drop in sales that will still cause severe difficulties for the affected businesses.

²⁵ 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.

²⁶ 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.

Thus companies faced with a 25% 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 Supplemental Trade Action used in these products, such that these companies will be forced to either increase retail prices or reduce profit margins on products impacted by the proposed duty, or may decide to eliminate affected products entirely.

In any of the above scenarios consumers of these products will also be harmed by inclusion of the identified HTSUS subheadings in the Proposed Supplemental Trade Action, 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 percent²⁷ to 76 percent.²⁸ Analyses have also been conducted on various American subpopulations, and reports have found supplement use by 33 percent of children and adolescents,²⁹ 66 percent of college students,³⁰ and 70 percent in Americans over 60 years of age.³¹

Thus any increase in costs or reduction in choices of dietary supplements would affect many million American consumers, and would have negative impacts in all U.S. age categories. And 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.

Harming U.S. businesses and American consumers is inconsistent with USTR's own criteria for selecting appropriate Chinese exports for imposition of duties

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 USTR reported that the trade analysts who identified the products for listing in the Initial Trade Action 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

²⁷ Kantor ED *et al.* October 2016. Trends in dietary supplement use among US adults from 1999-2012. *JAMA* 316(14):1464-1474.

²⁸ CRN 2017 Annual Survey on Dietary Supplements; accessed on September 3, 2018 at <https://www.crnusa.org/resources/crn-2017-annual-survey-dietary-supplements>.

²⁹ 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.

³⁰ Lieberman HR *et al.* October 2015. Patterns of dietary supplement use among college students. *Clinical Nutrition* 34:976-985.

³¹ 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.

lowest consumer impact.”³² Similarly, in the June 20 Notice, 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...”³³ And USTR also noted in the July 17 Notice that the list of HTSUS subheadings included in the Proposed Supplemental Trade Action was developed 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.³⁴ Also, in its requests for comments to the April 6 Notice, the June 20 Notice, and the July 17 Notice, 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.³⁵

It is thus AHPA’s strong view that no matter how well intentioned USTR has been in the process of developing the Proposed Supplemental Trade Action 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 U.S. 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...”³⁶ and “...to assist industries, firm, workers, and communities to adjust to changes in international trade flows.”³⁷

³² 83 FR 14906 at 14907.

³³ 83 FR 28710 at 28711.

³⁴ 83 FR 33608 at 33610.

³⁵ 83 FR 14906 at 14908; 83 FR 28710 at 28712; and 83 FR 33608 at 33609.

³⁶ 19 U.S.C. 2102(1).

³⁷ 19 U.S.C. 2102(4).

The HTSUS subheadings relevant to the dietary supplements and herbal products industries are not relevant to China’s “Made in China 2025” policy

In providing its explanation for how the lists of specific HTSUS subheadings included in the proposed trade actions that would impose additional *ad valorem* duties on certain imports from China, USTR noted that trade analysts initiated this process by identifying products that benefit from Chinese industrial policies, including China’s “Made in China 2025” policy.³⁸ And USTR later in this process acknowledged the need to establish a formal mechanism for exclusion of particular HTSUS subheadings from the additional duties proposed on Chinese exports in response to the section 301 investigation, partly in response to assertions by the public that certain specific products “were not strategically important or related to the ‘Made in China 2025’ program.”³⁹

The main focus of Made in China 2015 is on high-technology industries

The Made in China 2025 policy was written by China’s State Council on May 8, 2015 and released on May 19, 2015.⁴⁰ The document was identified as an “action plan for China’s implementation of the first decade of the strategy of manufacturing a strong country,” and identified ten key sectors in which this policy will vigorously promote breakthrough development; those ten sectors are:

1. A new generation of information technology industry;
2. High-end CNC (computer numerical control) machinery and robotics;
3. Aerospace equipment;
4. Marine engineering equipment and high-tech ships;
5. Advanced rail transit equipment;
6. Energy-saving and new energy vehicles;
7. Power-generating equipment;
8. Agricultural machinery and equipment;

³⁸ 83 FR 14906 at 14907.

³⁹ 83 FR 28710 at 28711.

⁴⁰ Notice of the State Council on Printing and Distributing “Made in China 2025” (国务院关于印发《中国制造 2025》的通知); May 19, 2015. Accessed at http://www.gov.cn/zhengce/content/2015-05/19/content_9784.htm on September 1, 2018; translation by Google Chrome.

9. New materials; and
10. Biomedicine and high-performance medical devices.

AHPA notes, however, that none of the HTSUS subheadings included in the Proposed Supplemental Trade Action issued by USTR and listed in the Annex in the July 17 Notice that AHPA has identified above as relevant to materials used in dietary supplements and herbal products manufactured or marketed in the United States are in any way related to the ten sectors that are the focus of the planned or intended breakthrough developments addressed in China's Made in China 2025 policy.

According to the U.S. Chamber of Commerce, the Chinese government will implement or continue programs and policies that favor domestic suppliers and limit market access for foreign companies that wish to compete in each of the sectors that are the focus of Made in China 2025.⁴¹ AHPA has no position on the programs and policies that the government of China will use to support Made in China 2025, as reported in the Chamber's report, nor on the appropriate response of the United States to China's actions in this matter.

AHPA requests removal of HTSUS subheadings relevant to the dietary supplements and herbal products industries from the Proposed Supplemental Trade Action

AHPA is requesting by these comments that the Trade Representative remove from the Proposed Supplemental Trade Action all of the HTSUS subheadings listed in the Annex in the July 17 Notice that are identified in these comments as relevant to ingredients (and the several listed packing materials) used in dietary supplements and other herbal products manufactured or marketed in the United States. There are numerous rationales to support this request, summarized below.

Harm to U.S. businesses and American consumers

As described in detail above, AHPA has significant concerns regarding possible 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 Supplemental Trade

⁴¹ United States Chamber of Commerce. 2017. "Made in China 2025: Global ambitions built on local protections."

Action as listed in the Annex in the July 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 views this single point as providing the most convincing rationale to support its request for USTR to simply remove all of the subject HTSUS subheadings from the Proposed Supplemental Trade Action. AHPA nonetheless provides below additional points in support of this request.

The process for requesting exclusions does not appear to apply to subheadings listed in the Annex in the July 17 Notice

In the Exclusions Process Notice issued on July 11, 2018, USTR set out specific procedures and criteria that must be undertaken to request exclusion of any particular HTSUS subheading from Annex A in the June 20 Notice. USTR stated in this Notice that it must receive requests relevant to these procedures and criteria to exclude any particular product by October 9, 2018.⁴²

The Exclusions Process Notice predated issuance on July 17, 2018 of the Proposed Supplemental Trade Action, and identified relevance only to the those subheadings “set out in Annex A” of the June 20 Notice. AHPA cannot therefore assume that USTR intends to apply the same process, procedures and criteria to requests for exclusion of HTSUS subheadings identified in the Annex in the July 17 Notice. This is particularly relevant to AHPA’s interests and the interests of AHPA’s members, as all of the HTSUS subheadings identified in these comments as relevant to materials used in dietary supplements and other herbal products manufactured or marketed in the U.S. are listed in the Annex in the July 17 Notice.

⁴² 83 FR 32181 at 32182. The Exclusions Process Notice stated its relevance to duties of “a particular product classified within a HTSUS subheading set out in Annex A of the notice published at 83 FR 28710 (June 20, 2018).” This Annex A lists just the 818 HTSUS subheadings that were included in the Initial Trade Action issued in the April 6 Notice and retained after USTR’s review of comments to this initial list. Thus it appears that USTR has not to date set out procedures and criteria to allow for requests for exclusion of any of the 284 HTSUS subheadings listed in Annex C of the June 20 Notice or of the 6,031 subheadings listed in the Annex issued subsequently in the July 17 Notice.

AHPA is not, however, requesting that USTR modify the procedures and criteria issued in the Exclusions Process Notice to make this process also relevant to the HTSUS subheadings identified in the Annex in the July 17 Notice. AHPA believes that adherence to the procedures and criteria established as relevant to requests for exclusion of subheadings listed in Annex A in the June 20 Notice would be overly tedious and prohibitively expensive to complete for the many HTSUS subheadings that AHPA is requesting be excluded from imposition of additional *ad valorem* duties. In particular, it would not be at all feasible to complete such requests prior to the October 9, 2018 deadline for submission of such requests relative to subheadings listed in Annex A in the June 20 Notice.

No relevance to Made in China 2025

As previously noted in these comments, prominent attention has been paid to Made in China 2025 by USTR and the trade analysts engaged in development of the lists of HTSUS subheadings proposed to be subject to additional 25 percent *ad valorem* duty in the matter of the section 301 investigation. But the focus on this Chinese government policy is not at all relevant to the HTSUS subheadings listed in the Annex in the July 17 Notice that are identified in these comments as relevant to the U.S. herbal and dietary supplement trades. These subheadings should therefore be removed from the Proposed Supplemental Trade Action.

Concluding statement

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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