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**Steptoe**  
STEPTOE & JOHNSON LLP

May 10, 2013

Douglas Bell  
Chair, Trade Policy Staff Committee  
Office of the U.S. Trade Representative  
Executive Office of the President  
600 17<sup>th</sup> Street, NW  
Washington, D. C. 20508

**Re: Submission of the American Herbal Products Association in support of U.S.  
negotiation of a Transatlantic Trade & Investment Partnership**

Dear Mr. Bell:

This submission is presented on behalf of the American Herbal Products Association (AHPA), which consists of 241 active member companies engaged in the production and sale of herbal dietary supplements (membership list attached). Steptoe & Johnson LLP is counsel to AHPA in connection with the negotiations between the United States and the European Union, looking to the creation of a Transatlantic Trade & Investment Partnership (TTIP).

The purpose of this submission is to urge that the United States raise, as a priority issue in the TTIP negotiations, the need to reform the European Union's regulatory scheme concerning herbal dietary supplements, which today acts as an unreasonable and scientifically unjustified barrier to AHPA members' ability to export to and sell in the European Union.

Effect on U.S. Commerce. The market for herbal dietary supplements in the United States – as well as the potential market for these products in Europe – is large. The current U.S. market, at retail, is approximately \$5 billion. Because of the EU's restrictive regulatory scheme, sales of these products in the EU are much smaller. AHPA will gather and submit more precise figures on the volume of sales in both markets.

Herbal Dietary Supplements are, as the name implies, supplements that provide nutritional support for the human diet. They are not marketed as products that diagnose, treat, cure or prevent any disease. They are sold in a variety of forms: tablets, capsules, gels, liquids, powders, etc. and may consist only of herbal ingredients or of herbal ingredients combined with other ingredients, such as vitamins, minerals, amino acids and such dietary supplements as fish oil, glucosamine, etc. Herbal dietary supplements are allowed to be sold in the United States without restricted access through a variety of channels of trade, including retail stores, online sales and direct selling.

The Need To Reform the EU Regulatory Regime and Harmonize It With the U.S. Regulatory Approach. Herbal dietary supplements, as noted above, are not drugs or medicines. Because they do not purport to diagnose, treat, cure or prevent diseases, there is no logical or scientific basis to apply to them the regulatory restrictions applicable to drugs. And therefore the U.S. statute (21 U.S.C. §§321ff) treats them as dietary supplements, not drugs. The effect of this is that herbal dietary supplements are subject to limited restrictions:

- Marketing claims must (1) be truthful, (2) substantiated by the marketer, (3) not represent that the product is a drug or that it will “diagnose, treat, cure or prevent disease,” (4) be accompanied by a disclaimer and (5) be notified to the FDA within 30 days of marketing,
- Products must be manufactured in compliance with federal cGMP, and
- Serious adverse events must be reported to FDA

In addition, a few constituents may not be contained in the supplement:

- tobacco,
- ephedrine – containing herbs,
- herbs that contain aristolochic acid,
- herbs that contain toxic pyrrolizidine alkaloids, and
- other herbs determined to be toxic (e.g., oleander or poison ivy)

In contrast to the U.S. regime, which allows the free sale of herbal dietary supplements subject only to these specified, limited protective provisions, the EU treats the great majority of these supplements under their regulations applicable to drugs. This requires an approval process that is difficult to meet and expensive to comply with. We will provide more detail on the specifics in our next submission, but the important point is the application to dietary supplements of a regime that has scientific justification only where there is a need to be sure that the products

are effective in preventing or treating diseases. Where a product is not sold for such medicinal purposes, the use of that restrictive regulatory regime has no scientific or rational basis and, when applied to imports, is simply an impermissible trade barrier.

Argument. A major premise of this EU-US TTIP negotiation is that regulations should be based on sound science in determining the threat of harm posed by the sale of a product and the nature and degree of regulations necessary to prevent that harm. In this regard, the U.S. and EU have committed to follow the principles of the World Trade Organization Agreement on Sanitary and Phytosanitary Measures (the “SPS Agreement”).

The EU regulatory scheme is not consistent with sound science or with the dictates of the SPS Agreement. There has been no scientific study done by the EU that establishes a risk of harm from the taking of any of these products. It follows, therefore, that the regulatory scheme is not crafted to address a threat of harm, much less to do so in ways least disruptive of trade.

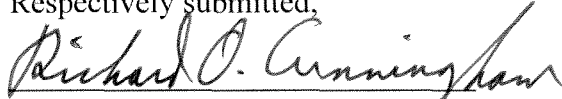
It should be emphasized that no issue relating to these products brings into play the so-called “precautionary principle” that the EU purports to follow in its drug, health, safety and environmental regulatory schemes. Here there is no claim that these products have the potential to cause harm when consumed by humans. Therefore there is no threat for which a “precautionary” approach is warranted.

The closest thing there is to any conceivable concern about these products in that some people, believing them to be effective against disease or other medical conditions, might take these products instead of taking needed drugs or medical treatments. However, to the extent that this concern exists, it is fully addressed by a provision such as that contained in the U.S. regulatory scheme – namely, that sales of these products be accompanied by a clear disclaimer that they are not represented as curative of any disease or medical condition.

Recommendation. AHPA recommends that USTR make this a priority agenda item in the TTIP negotiations. The foreclosure of market access through excessive and unjustified regulation is clear. To the extent that the EU regime is more restrictive than the U.S. regime for herbal dietary supplements, and particularly to the extent that the EU wrongly applies to these products requirements that are appropriately applied only to drugs, the EU regime should be harmonized with the U.S. regulatory regime. The value of annual trade unreasonably foreclosed is in billions of dollars.

Both the clarity of the issue and the value of foreclosed access to the EU market make it clear that this should be a priority issue.

Respectively submitted,



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### AHPA - ACTIVE MEMBERS

A.M. Todd Botanicals
AD Medicine International LTD
Alkemists Laboratories, Inc.
Amazon Herb Company
American Botanicals
American Nutritional Corporation
Animal Essentials, Inc.
Arise & Shine Herbal Products, Inc.
Aspen Group, Inc.
Auburn Laboratories, Inc.
Aveda Corporation
Ayush Herbs
Azile, LLC
B&K International / Famarco Ltd.
Bactolac Pharmaceuticals Inc.
Banyan Botanicals
Barrington Chemical Corporation
Bay Area Safe Alternatives
BDS Natural Products
Beehive Botanicals, Inc.
Berkeley Patients Care Collective
BI Nutraceuticals
Bighorn Botanicals, Inc.
Bio Essence Corporation
Bio-Botanica, Inc.
Bioforce USA
BioRay, Inc.
Biotropics Malaysia
Blue Poppy Enterprises
BodyBuilding.com LLC
Botanics Trading, LLC
Classical Pearls
CMSI, Inc.
Coltsfoot, Inc.
Concordia Partners LLC
Cortex Scientific Botanicals (Botanica Bio)
Crane Herb Company
Crila Health
Dixie Elixirs & Edibles
DMD Pharmaceuticals
Dockside Cooperative
Dr. Bronner's Magic Soaps
Draco Natural Products
Dragon Herbs
Driven Sports
Duncan's Botanical Products, Inc.
Dymatize
Earth Mama Angel Baby
Earthrise Nutritionals LLC
East West Tea Company, LLC (Yogi Products)
Emerald Bay Outreach

Emerson Ecologics
Empirical Labs, Inc.
Energique, Inc.
Enzyme Formulations
EuroPharma
Evergreen Herbs & Medical Supplies
Exercise Scientist, LLC
FanPharma (Shanghai FanPharma)
Far East Summit, LLC
Farmacy, The
First Fishery Developments
Flora, Inc.
Flower Essence Services
Food Movement Co., The
FoodScience Corp
Frontier Natural Products Co-op
Gaia Herbs, Inc.
Garuda International, Inc.
Gaspari Nutrition
Gemini Pharmaceuticals, Inc.
General Nutrition Centers (GNC)
Geni Herbs (Verdure Sciences)
Ginco International & The Ginseng Co.
Global Marketing Associates, Inc. (Prince of Peace)
Golden Biotechnology Corporation
Golden Flower Chinese Herbs
Good Herbs
Guayaki S.R.P., Inc.
Hain Celestial Group
Hansen Beverage Company
Harborside Health Center
Harris Tea Company
Health Concerns
Healthy Body Svc, Inc (Allmax)
Hebron USA
Herb Pharm
HerbaKraft, Inc.
Herbal Teas International
Herbalife International
Herbalist & Alchemist, Inc.
Herbalist, Inc., The
Herbs America, Inc.
Herbs, Etc., Inc.
Heron Botanicals
Himalaya USA
Hsu's Ginseng Ent.
IdeaSphere
Indena USA, Inc.
Indiana Botanic Gardens, Inc.
International Botanical Ingredients
IonLabs
Iovate Health Sciences

Irwin Naturals
Jamieson Laboratories Limited
Kan Herb Company
King Bio
Komal Herbals, Inc.
KPC Products, Inc.
Kroeger Herb
Laboratorios Mixim, S.A. de C.V.
Lang Naturals
Laro Suplidora de Nutricion S.A.
Lief Organics
LifePlus International (Eurark LLC)
Maharishi Ayurveda Products Intl Inc
Market America
Mars Botanical
Martin Bauer, Inc.
Mayway Corporation
Medical Horizons, Inc.
Memory Secret, Inc.
Meridian Trading Company
Metagenics, Inc.
Michigan Holistic Health
Min Tong Herbs, Inc.
MOLEAC
Moringa Source, LLC
Motherlove Herbal Company
Mountain Meadow Herbs, Inc.
Mountain Rose Herbs
Muscle Warfare, Inc.
Mushroom Wisdom (was Maitake Products, Inc.)
Mushroom Harvest
Natreon, Inc.
Natura Health Products, Inc.
Natural Alternatives International, Inc.
Natural Factors Nutritional Products
Natural Relief, Inc.
Natural Source International Ltd.
Nature's Formulary, LLC
Nature's Products, Inc.
Nature's Wonders Naturopathic, Inc
Naturex, Inc.
NBTY, Inc.
New Chapter, Inc.
New Sun, Inc
Neways International
NHK Laboratories, Inc.
Northland Ginseng Farms, Inc.
NovaCare LLC
Novel Ingredient Services, LLC
NOW Foods
Nuherbs Company
Nutraceuticals International LLC

Nutraquest (Prosource)
Ohio River Ginseng & Herb
Oregon's Wild Harvest
Organic Farm Girl, Inc.
Organic India USA
Oriental Herb Company
Origana Nutraceuticals
Ortho Molecular Products
P.L. Thomas
Pacific Botanicals, LLC
Pacific Nutritional, Inc.
Paradise Herbs
Paragon Laboratories
Peace in Medicine
Perrigo Company
Planetary Herbals (Threshold Enterprises)
Plantaphile Ltd.
PlusPharma, Inc.
Pro-Form Laboratories
Prothera Inc.
Pukka Herbs
Purapharm International (HK) Ltd.
Pure Encapsulations
Pure Ground Ingredients
Purest Colloids, Inc.
Purity Products
Qtrade Teas & Herbs
QuantaFoods Association
Quantum Herbal Products
Quantum, Inc.
Rainbow Light Nutritional Systems
Randal Optimal Nutrients, Inc.
Redd Remedies
Reliance Vitamin Company, Inc.
Remedy Compassion Center
Restorative Medacine (WTSmed, Inc.)
Ridge Runner Trading Company, Inc.
Ridgecrest Herbals
Sabinsa Corporation
San Francisco Herb & Natural Food Company
Savesta Life Sciences, Inc.
Schwabe North America (Nature's Way + Enzy)
Seawolf Consultants Group
Sedona Tea Blends
Shree Dhootapapeshwar Ltd.
Skyherb
Soft Gel Technologies Inc.
Solgar Vitamin & Herb
SPARC, San Fransico Patient & Resource Center
Springland Trading
St. Francis Herb Farm
Standard Process Inc. - MediHerb



Stiebs
Strategic Sourcing, Inc.
Strong Ginseng & Herbs Industries Co. Ltd.
Suan Farma
Sunrider Corporation
Sunrise Global Trading, LLC
Swanson Health Products
Synergy Production Laboratories
Systemic Formulas, Inc.
Tango Advanced Nutrition, Inc.
Taos Herb Company
Tazo Tea (Starbucks Coffee Co.)
Terra Botanica
Tishcon Corporation
Tom's of Maine, Inc.
Trace Minerals Research
Traditional Medicinals
Trout Lake Farm LLC
True Botanica, LLC
Ultimate Nutrition
Universal Nutrition
Urban Moonshine
USP Labs LLC
UST Corporation
Valensa International
Vitality Works, Inc.
Vitamin Research Products, Inc.
Vitamin Shoppe
Wakunaga of America Company
Western Botanicals
Wisdom Natural Brands
Wise Woman Herbals (EarthLab, Inc.)
Xi'an Yooqi Plant Essence Extraction Co.
Yellow Emperor, Inc.