Richard N. Holwill ♦ Vice President – Public Policy ♦ 419 New Jersey Avenue, SE ♦ Washington, DC 20003
202.547.0300 ♦ Fax 616.682.4076 ♦ richard.holwill@Alticor.com

May 10, 2013

Mr. Douglas Bell
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Filed electronically at www.regulations.gov

RE: Amway Response: Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement; Federal Register Document Number USTR-2013-0019

Dear Mr. Bell:

We welcome the United States Trade Representative's announcement that it has notified Congress of the Administration's intention to enter into negotiations for the Transatlantic Trade and Investment Partnership (TTIP). We are optimistic that the agreement will succeed in: resolving hindrances to direct selling distribution services; promoting regulatory cooperation and coherence; and reducing technical barriers to trade that limit market access for Amway products.

Amway Corporation is a major U.S. exporter and the leader of the global direct selling industry with $11.3 billion in annual sales and over 20,000 employees globally. Amway operates in 28 European countries, from Portugal over to Turkey, and from Scandinavia to Greece. Amway's 1,200 employees and over 500,000 Business Owners in Europe do business in some 25 languages. Amway's European headquarters are located near Munich, Germany, and a shared Service Centre for finance, IT and marketing communications was recently established in Krakow, Poland. In 2012, the European markets brought in approximately $350 million.

With this presence in Europe and the EU, Amway is eager to see the Transatlantic Trade and Investment Partnership move forward to address the regulatory issues that form barriers to our exports and to our sales system in the EU. We anticipate that removal of these barriers would result in a significant increase in our sales in the EU. As such, this memorandum will address areas of concern in both services and regulatory cooperation/coherence.

I. Services

Together with other direct selling companies, Amway has previously submitted its comments to USTR on the International Services Agreement (ISA) and believes that our proposal for the ISA should be included in the TTIP negotiations. We support the goal of enabling U.S. service suppliers to compete on the basis of quality and competence rather than nationality. We appreciate that the scope of TTIP will be comprehensive, permitting the coverage of all services, including direct selling as a distribution service.

In anticipation of a successful final agreement, we have drafted language (see attachment) in the form of an Annex on Distribution Services, Direct Selling. We believe that this Annex language, which defines direct selling and calls for non-discriminatory treatment would be a significant step forward for this important U.S. industry.

With regard to Distribution Services, direct selling companies are quite concerned about restrictions on the types of products than can be distributed in Europe through the direct selling channel. Some EU Member States prohibit or limit the ability of companies to sell nutritional supplements such as vitamins, botanical and herbal products through this channel – even though they are sold freely to consumers without a prescription or special authorization.

Sale of such products should not be restricted based merely on the sales channel used by the company. Products that can be sold freely to consumers without a prescription or special authorizations should also be allowed for sale through direct selling channels. We believe that these restrictions should be lifted as a matter of right.

II. Regulatory Cooperation/Coherence

In general: We propose that USTR seek product-specific Annexes under the "sectorial approach" used in the TPP for the TBT and SPS chapters of TTIP. We believe that many of the regulatory issues for cosmetics and for dietary supplements are unique and best solved using this approach. Cosmetics are included in TPP, and dietary supplements should also be included in TTIP in the form of a sectorial approach.

A. Regulation of Dietary Supplements, Including Restrictions on Products Containing "Botanicals"

We are concerned that the EU's regulation of dietary supplements, especially botanicals (plant ingredients) is not based on risk analysis. The EU categorizes some dietary supplements, including botanicals, as high risk pharmaceuticals. It then requires an expensive and lengthy registration and scientific review process that is appropriate for high risk medicines. This system is not necessary for food supplements, including botanicals. In Europe over 56 percent of Amway's Nutrilite® products contain a botanical ingredient in the formulation, including the top three selling products.

Through TTIP, we request that the USG negotiators move toward a harmonized cooperative regulatory approach between the USG and the EU on regulation of food supplements and, in particular, botanicals.

The EU regulations covering botanicals are not harmonized and are currently undergoing review by the European Commission. Amway is actively participating in the industry educational effort to achieve a harmonized European market. The goal of this effort is to achieve a liberalized market for botanicals regulated under food law rather than medicinal laws as is the case in some Member States today.

The Member States have recently provided feedback to the European Commission on the future regulatory approach to botanicals (medicinal/food law). The majority of European countries have a list of approved botanicals for food supplements. The Countries with a more liberal approach to botanicals are, France, Italy and Belgium. Countries with a more restrictive approach based on restrictive lists of botanicals sold as traditional herbal medicines are, Greece, Spain, Austria, Poland and Denmark. The majority of other Member States authorize some botanicals under food law and others as traditional herbal medicines based on an approved list of substances. Amway supports proposals to allow the use of all botanical substances that have been shown not to be harmful provided they are manufactured according to Good Manufacturing Practices regarding quality and safety.

FDA regulates dietary supplements as "foods" and not drugs – and treats botanicals as dietary supplements, not medicines. FDA does not list products that can be marketed or that cannot be marketed. Instead, if there is a problem with a specific product, it orders the removal of that product from the market with warnings issued to consumers. We strongly support this approach to the regulation of dietary supplements.

In the United States botanicals are regulated as low-risk products. Registration is not required and the products can be marketed as long as the labels are truthful, there are no consumer complaints about illness, and the production meets standards of quality. The company selling the product is responsible for determining that its dietary supplements are safe and that any representations or claims made about the products are appropriately documented. Thus, dietary supplements do not need FDA approval before they are sold in the United States. We hope to see this approach endorsed in the TTIP negotiations.

B. REACH

The EU chemical registration and approval regime, known as REACH, creates unreasonable burdens on U.S. exporters to the EU. Because REACH classifies all importers as chemical producers, the regulation creates substantial barriers to the importation of finished product even though comparable "downstream users" manufactured in the EU are not subject to REACH registration. This bias toward EU production disadvantages U.S. companies that distribute products in Europe even if they use chemically identical substances. We believe that this bias in REACH is a Technical Barrier to Trade worthy of a challenge in the WTO.

We support the following approach to REACH:

- Request that the EU establish ombudsmen in all of their key regulatory agencies, especially ECHA, modelled after the EPA's small business ombudsman, as a way to expedite a direct dialogue among regulatory authorities and their commercial stakeholders.
- Encourage ECHA to be open to a dialogue with U.S. companies disadvantaged by this regulation.
- Require mutual recognition of all test data.
- Strive for uniformity across all member states, with no additional requirements by some Member States.
- Ensure that required data sharing arrangements are equitable and transparent.
- Require that initial results of the review of substance under Community Rolling Action Plan (CORAP) be made available to U.S. companies even if they are not yet registrants. The refusal to share CORAP data puts those intending to register substances at a serious disadvantage as this bars them from the ability to make comments prior to finalization.

Reciprocity and mutual recognition of chemical approvals would alleviate some of the burdens of REACH. If a product containing a chemical compound is freely offered for sale in the United States, it should be authorized for sale in the EU without additional chemical ingredient registration. Chemical compounds manufactured in the United States in accord with GMP standards and produced by approved U.S. entities should be allowed by the EU without a further approval process.

C. Implementing Regulations for International Treaty on Genetic Resources (Nagoya Protocol)

Background: The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Protocol) is a global agreement that implements the access and benefit-sharing obligations of the Convention on Biological Diversity (CBD). It was adopted in Nagoya, Japan in October 2010 after six years of negotiations. The Protocol's objective is the fair and equitable sharing of benefits arising from the use of genetic resources. Genetic resources from plants, animals and microorganisms are used in the development of specialty enzymes, enhanced genes, or small molecules. Amway ingredients might now or in the future be covered by the Protocol.

The EU is taking a leading role, among signatory countries, in developing implementing regulations toward formal ratification of the Nagoya Protocol. These regulations have the potential to impose new import-export documentation requirements for tracing ingredient sourcing. This process is designed to form a basis for challenge on patent applications. Amway supports the "due diligence" approach being taken in the EU Draft Regulations for documenting compliance with the Protocol.

The Nagoya Protocol also requires each jurisdiction to establish one or more "checkpoints" to monitor compliance. Amway strongly recommends that customs authorities not be designated to function as the checkpoints as they do not have the appropriate expertise. If the customs

authorities, of either the importing or exporting country, become involved the compliance review will be very inefficient and will very likely result in significant shipping and clearance delays.

We are concerned that the EU Draft Regulations may be amended as the draft regulation advances through Parliament. Our greatest concern is that some outside groups are advocating draconian changes to the very reasonable current draft with regard to retroactive application of the protocol to genetic resources accessed before the Protocol went into force. These substances are exempt in the draft regulation and should remain exempt. Related to this is the evolving discussion for a Global Multilateral Benefit Sharing Mechanism (GMBSM), which would be an industry fund to help share benefits. The GMBSM, which will likely be controversial and unenforceable, could be applied retroactively to current genetic resources. We urge caution on this point and ask that current genetic resources remain exempt from the Protocol.

In general, Amway supports the EU Draft Regulation in the form most recently published. We urge the USG to oppose measures that would be more restrictive than the current text.

D. EFSA Regulatory Approval of Claims relating to Health Maintenance Products

Many elements of the EC Nutrition and Health Claims Regulation (NHCR) remain unresolved or open to interpretation. This creates uncertainty for companies and enforcement authorities. The procedures and processes for scientific assessment included in the NHCR have been combined into a complicated process that leaves companies with little opportunity to make legitimate claims for health-maintenance products. In addition the pharmaceutical standards adopted by the European Food Safety Agency (EFSA) to assess health claims for food products have proven to be unworkable and unsuitable for food-product approvals and requirements. We recommend a process for the evaluation of health-maintenance claims that would permit companies to rely on recognized academic studies related to the benefits of health-maintenance products, which are not intended to cure preexisting diseases or medical conditions.

E. GMO Tolerance Level

The EU regulatory system for GMOs requires pre-approval for GMO ingredients. Approval of common products has been delayed because the Member States have been unable to reach a consensus on the sale of safe GMO products. The very quick approval process in the United States stands in sharp contrast to the process in the EU. We are concerned that future market access for Amway products may be at risk as a consequence of the controversy among EU Member States.

Amway supports the measures introduced by the EU that require disclosure of a GMO presence for products with GMO levels in excess of 0.9%. Amway supports the principle that food with very low levels of GMO can be sold in the EU without labels. If a specific level is established for non-labeled food, it must be at a reasonable level.

Amway supports the position of the USG that GMO products do not pose a threat to human health. That said, we manufacture our products to the EU standards for acceptable GMO levels.

Again, Amway meets EU labeling requirements. We believe, however, that a further tightening on acceptable levels of GMO products is unneeded and unwise. TTIP should bar further restrictions on GMO ingredients absent clear scientific evidence of harm.

F. Nanotechnology

As an emerging technology with the potential to create major technological breakthroughs, the USG should work with the EU to ensure that unnecessary and costly regulation does not stifle this potential. The current EU position on nanotechnology is that, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Therefore, nanomaterials require a risk assessment on a case-by-case basis.

Amway uses nanomaterials as UV-filters in cosmetic applications, which is typical in these product categories. These uses have been consistently demonstrated as safe, both in consumer experience and in scientific review, including EU Scientific Committee for Consumer Safety. Amway strongly supports a case-by-case risk-assessment approach based on sound science. The USG and the EU should continue to work together to ensure that sound science is the basis for all decision-making on nanotechnologies. The USG should seek a commitment from the EU that no unjustified regulatory burdens will be put on nanotechnology, which the EU has identified it as "a key enabling technology."

G. EU Cosmetic Directive: Mutual Recognition

Although the EU Cosmetic Directive has more prescriptive elements than corresponding U.S. regulation, the regulation of cosmetics in both the EU and the United States has been demonstrably consistent resulting in a largely homogeneous offering of products. Therefore, it is logical that these common products should have mutual recognition of ingredients, commonly recognized nomenclature, mutually recognized labeling, and consistent enforcement of these harmonized rules across the EU. We support proposals to ensure mutual recognition of cosmetic products.

H. EU Cosmetics Directive: Animal Testing

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Cosmetics Directive) imposed a ban on: testing finished cosmetic products and ingredients on animals (testing ban); and, marketing finished cosmetic products that have been tested on animals or which contain ingredients that have been tested on animals (marketing ban). These provisions are contained in the Cosmetics Regulation that will replace the Cosmetics Directive as of 11 July 2013.

The testing ban on finished cosmetic products has been in effect since September 2004 and the testing ban on ingredients or combination of ingredients has been in effect since March 2009. The marketing ban has been in effect since 2009 for human-health effects with some exceptions. These were being phased-in as scientific developments made alternative tests available. However, in March 11 2013, the EU announced by Press Release that the marketing ban would

be in effect going forward for all specific health effects without respect to the availability of alternative non-animal tests.

Amway supports the efforts of the EU in identifying and implementing alternatives to animal testing. However, we note with concern that several of the required tests do not have alternatives identified. The European Commission has acknowledged this problem but has not addressed it. We believe that, until effective non-animal tests are available, industry should be permitted to conduct needed tests on animals to ensure that substances are safe for humans and not harmful to the environment.

I. Globally Harmonized System for Classification and Labeling of Chemicals (GHS)

The EU has opted for very rigorous rules regarding the classification and labeling of consumer products that exceeds all recognized obligations to warn consumers of potential hazards. The USG continues to use less prescriptive labeling requirements. The EU approach has not demonstrated any advantage to consumers. Amway encourages the harmonization of labeling requirements to allow for the recognition of U.S. warning formulations.

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) was conceived in 2002 at the UN World Summit on Sustainable Development and published in 2003. It addresses classification of chemicals by types of hazard and proposes harmonized hazard-warning formulations for labels and safety data sheets. It also provides a basis for a uniform global classification system for physical, environmental, health and safety information regarding hazardous chemicals in the preparation of Safety Data Sheets.

Both the USG and EU have implemented GHS in accord with their national laws and regulations. In the United States, the revised Hazard Communication Standard (HCS) will be in effect in June 2015. The EU regulations (EU CLP) were partially implemented on January 3, 2011, and will be in full force in June 2015. The European regulations (CLP Article 1.5) exempt certain products, including cosmetics, used in direct physical contact with the human body, are exempt when they are in the finished state and intended for the final user. However, the EU interpretation of "finished state and intended for the final user" is quite restrictive for cosmetics. We urge harmonization of the term "finished state" in the regulations of the two treaty partners.

J. Endocrine Disruptors

The OECD has established a *"Conceptual Framework for the testing and assessment of endocrine disrupting chemicals."* This framework is intended to ensure the safety of people and of the environment. Amway asks that the TTIP develop a coherent approach to identification of potential endocrine disruptors and to the prevention of any adverse effects from exposure to these substances. We urge negotiators to agree on a common basis for defining endocrine disruptors and for establishing a dose response that will achieve the common goal of "no observable effect levels" (NOELs). While it will be impossible to achieve this goal in treaty language, we urge the negotiators to establish a process through which common definitions and dose responses can be developed based upon sound scientific analysis.

K. Environmental Regulations

EU environmental regulations specific to each jurisdiction affect the chemistries used and subsequent product offerings. As part of the TTIP process, we urge a review of the impact of these regulations and harmonization standards among them. This will ensure that environmental safety and human health are protected without the imposition of arbitrary barriers to trade. This problem now exists with regard to member-state based restrictions on volatile organic materials and on the criteria for identifying environmental toxins. We hope to see language in TTIP that requires a review of new regulations with the partner jurisdictions.

L. Science-based Regulation

Both the EU and the USG have committed to sound science as the basis of any regulation for which there are scientific components. Amway strongly encourages consultation among key regulatory bodies prior to the issuance of regulations to ensure that they are indeed science-based. This would provide an opportunity to eliminate differences – including on the basis of the term "science-based" – prior to the issuance of divergent rules. We hope that an accord on this point would extend the development of a formal review process to consider the differences in approach between regulatory bodies and to harmonize systems to the extent possible.

***

We applaud the Administration's approach of making regulatory cooperation and coherence a priority goal for TTIP. An ambitious TTIP agreement, combined with a successful Trans Pacific Partnership agreement and an International Services Agreement, will provide an updated framework for international business and improve the ability of Amway and other companies to thrive in the global marketplace.

Thank you for your consideration of these comments.

Sincerely,

Richard Holwill
Vice President – Public Policy

ATTACHMENT

Annex

Distribution Services in The Trans-Atlantic Trade and Investment Partnership

1. For purposes of trade negotiations, *Direct Selling* or *Direct Sales* refers to a sales system through which companies engage individuals to provide sales and sales-support services to the company away from a fixed retail location. Direct Selling is distinguished from catalog and other direct marketing operations both by the point of sale (away from a fixed retail locations) and by its reliance on person-to-person sales which often include product demonstrations and training. Direct Selling may include compensation to Direct Sales distributors to recognize their own personal sales and sales by those distributers who are recruited, trained and otherwise supported by the primary distributor. These payments recognize the value of the marketing and sales-support services by primary distributors as measured by product sales.

2. In contrast, this commitment in no way limits a Party from imposing restrictions on fraudulent sales systems, including but not limited to:
    a. *Pyramid Schemes* in which participants give consideration for the opportunity to receive compensation that is derived primarily from the introduction of other participants into the scheme;
    b. *Inventory Loading Schemes* in which companies induce participants to purchase goods that cannot be resold or returned to the company; and,
    c. *Subscription Churn Schemes* in which the company earns funds primarily from entry fees paid by subscribers who do not stay in the business and not from product sales.

3. The Parties confirm their desire to maintain at least the level of market openness for direct sales, to include both sales and sales-support services by individuals on behalf of companies, that is in existence on the date this Agreement is signed. If a Party considers that the other Party is not maintaining such level of access, it may request consultations. The other Party shall afford adequate opportunity for consultations and, to the extent possible, shall provide information in response to inquiries regarding the level of access and any related matter.

4. Specific exclusions on products sold through this channel shall be limited to those products that are normally sold on a restrictive basis including firearms, prescription drugs and, in some cases, alcohol. The sale of goods normally sold freely to consumers without a prescription or special authorization (including food products, food and nutritional supplements in tablet, powder, liquid capsule form) shall not be prohibited from distribution through this channel.