U.S. – China HPA Health Products Association 美中健康产品协会

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Administrative Regulations for Nutritional Supplements and Information Requirement for Nutritional Supplements DRAFT

U.S. – China Health Products Association: Questions and Comments

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The U.S. – China Health Products Association (USCHPA) commends China's Food and Drug Administration (CFDA) for taking the necessary steps to begin reforming China's Health food industry. This is an important growth industry for China and plays a significant role in helping China's citizens lead a more healthy life and as a result will assist in decreasing medical care expenditures.

In advance, the association and its members thank CFDA for taking the time to read and consider USCHPA's questions and comments in regard to the "Administrative Regulations for Nutritional Supplements" and "Information Requirement for Nutritional Supplements" draft regulations that were made public by CFDA on November 5, 2014.

Please find below USCHPA's list of Questions and Comments for: "Information Requirement for Nutritional Supplements"

1. **Section 3:** discusses the testing requirements for finished products and requires them to be tested at "China approved testing facilities". How many testing facilities are there and other than stability testing for three consecutive batches, what other tests are required?

   USCHPA's concern is with timing to enter market. If there are not enough approved laboratories, there could be a large backlog, which would slow down the market entry process considerably.

   Has there been an investigation into how long the testing and all administrative procedures would take from start to finish for this new recording system?

2. **Section 4 Subsection 4:** discusses the vitamin content levels. Can a finished product contain the maximum level of the DRI? For example, could a calcium product for adults have a daily dose of 1000mg. of Calcium or a Vitamin C product have a daily dose of

500mg. as outlined in the "Classification and Acceptable Daily Intake of Nutritional Supplements (I)"?

3. **Section 5:** uses the terminology "health food product" and not the term "nutritional supplement". As USCHPA understands, "health food product" refers to products that require a registration from CFDA known in the industry as the "blue hat registration".

   With this in mind, USCHPA requests some clarity between these two terms. Also will the "blue hat" registration system still exist?

   If the "blue hat" system will still exist, how will these two categories co-exist and what about all the vitamin and mineral supplements that are already in the market with a "blue hat" registration. How will this new legislation affect these products?

4. **Section 5 (Health Function Section 2):** What are the allowable claims for vitamins and minerals? Will there be a list of the approved allowable claims?

5. **Section 5 (Directions for Use Section 4):** Mentions that the format shall be in tablets, capsule, granules or liquid. What about soft-gel capsule, chewable, powders, effervescent, gummy (gelatin), fast dissolving tablets/strips (sublingual) dosage forms?

Please find below USCHPA's list of Questions and Comments for: "Administrative Regulations for Nutritional Supplements"

1. **Article 4:** Imported products must have more than one year overseas production and marketing record.

   This creates an unfair advantage for domestic companies, as they are not required to have one-year production or marketing record. This article's wording creates a barrier to trade for the below reasons. The association asks China FDA to reconsider this article and its wording.

   a) New foreign companies and/or products would have to wait one year before attempting to enter China. A new domestic company and/or product would be allowed to immediately record the product with China FDA without waiting one year.

   b) Many foreign products contain other ingredients and or nutrient levels that do not meet China FDA's regulations, so foreign companies would have to create a new product specifically for China. This new "specific for China" product would not be able to generate a record of marketing / sales because consumers in the home market would not buy it due to its lower potency and less effective formula.

2. **<u>Article 6 Section 2</u>**: States that nutrients extracted from edible parts of food must not contain other bioactive substances with effective dose.

   Does this statement mean that if a company is extracting for example vitamin C from fruits they could not include the bioflavonoids or other naturally occurring constituents?

   Can China FDA clarify this?

3. **<u>Article 9:</u>** States that manufacturing and technical requirements should meet national standard. For imported products, does this mean country of origin standard or China standard?

The term "Ying Yang Su" (营养素) is translated into English as "nutrient", which is defined as "a substance that provides nourishment essential for growth and the maintenance of life"[1]. This definition is very broad and would include all manner of nutrition to keep an organism alive, healthy and thriving.

USCHPA requests CFDA to expand the list of approved nutritional supplements to include not only vitamins and minerals, but other nutrients that are vital to human health such as trace minerals, amino acids, Coenzyme Q-10 and fatty acids in all their forms such as omega 3-6-7-9, DHA/EPA/CLA/ALA/LA etc. Also ingredients that are already approved as food and are known to have benefits to human health such as lutein, lycopene, pre and probiotics, fibers, ginseng, krill oil etc. This is by no means an all inclusive list, but USCHPA encourages CFDA to consider adding ingredients that are already approved as food / food ingredients by the Ministry of Health now called National Health and Family Planning Commission.

Without these other nutrients available for use, this new proposed nutritional supplement system would be excluding hundreds of ingredients that would be beneficial to the health of Chinese citizens.

Furthermore, if an ingredient is approved for use in foods in China then taking it in a dosage form of a capsule, tablet, powder, liquid, chewable, granule, gummy, effervescent, fast dissolving tablet or strip would be just as beneficial if not more so in some cases.

For example, probiotics are available widely in China in yogurt and other beverages. However, diabetics are not able to consume these beverages due to their high level of added sugar. Also people attempting to lose weight should avoid these high calorie sugary beverages. In both these examples, nutritional supplements in the dosage forms of capsule, tablet, powder, liquid, chewable, granule, gummy, effervescent, fast dissolving tablet or strip would not only be beneficial, but essential for the health of these two groups.

[1] *http://www.oxforddictionaries.com/us/definition/american_english/nutrient?searchDictCode=all*

USCHPA thanks CFDA for taking the time to read the questions and comments in this report. Please feel free to contact USCHPA directly if there is need of clarification or there is need to collect further comments. The association is more than happy to share further information.

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