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July 12, 2013

**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues**
**Docket No. FDA-2011-D-0376 --- 76 Fed. Reg. 39111 (July 5, 2011)**

The Consumer Healthcare Products Association (CHPA) is the 132-year old trade association representing manufacturers and distributors of nonprescription or over-the-counter (OTC) medicines. CHPA is also one of a number of national trade associations representing manufacturers and distributors of dietary supplements in the United States. We take this opportunity to voice our support of comments submitted by the Council for Responsible Nutrition (CRN) on May 7, 2013 regarding the appropriate interpretation of the term "chemically altered" under Section 413(a)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Dietary Supplement Health and Education Act (DSHEA) with respect to when a New Dietary Ingredient (NDI) Notification will be required. The comments submitted by CRN address a topic previously discussed in meetings held between the Food and Drug Administration (FDA) and the five dietary supplement trade associations (American Herbal Products Association, Consumer Healthcare Products Association, Council for Responsible Nutrition, Natural Products Association and the United Natural Products Alliance) in which the agency requested specific examples of manufacturing steps that would cause an existing dietary ingredient to be chemically altered (or conversely, not chemically altered) within the meaning of Section 413(a)(1).

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The CRN submission advances the position that determination of whether an ingredient should be considered "chemically altered" for the purpose of determining the need for an NDI under DSHEA should be based on the resulting ingredient and not the specific manufacturing process used to produce the ingredient. More specifically, to be considered chemically altered, the chemical structure of the ingredient should be different and result in a demonstrable potential effect on the safety of the ingredient when used as intended. This approach is in accord with FDA's stance on manufacturing process changes for other food ingredients contained in an April 2012 draft guidance document[1] (FDA-2011-D-0490; FDA Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives).

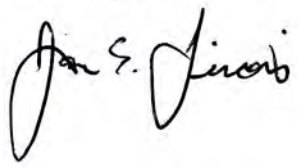
For food or color additives, FDA's draft guidance (FDA-2011-D-0490) provides a number of steps to determine when a change in the manufacturing process should require a new petition for FDA approval, including determining what changes have been made to the identity of the food substance as a result of a change in the manufacturing process. Potential impacts of a change in identity of the food substance should then be determined (i.e., if necessary, a safety assessment should be conducted). Of note, this guidance only recommends a submission to FDA (for food ingredients and food-contact substances) when the manufacturing change alters the chemical structure producing an end product which may potentially create an issue concerning the safety of the product for its intended conditions of use.

In sum, CHPA supports the position taken by CRN in their recent comments to the docket concerning the definition of a "chemically altered" dietary ingredient. The need for a NDI notification should encompass not only a change in the chemical structure of the dietary ingredient; but should also create a demonstrable and material effect on the safety profile of the ingredient when used as intended in a dietary supplement. This approach is consistent with the position taken by FDA in their recent draft guidance on changes in the manufacturing process for other food ingredients and food-contact materials.

[1] http://www.fda.gov/downloads/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM300927.pdf

Focusing on the chemical identity and safety of the resulting dietary ingredient rather than establishing a list of manufacturing steps or processes that do not chemically alter an ingredient should result in enhanced efficiency while maintaining safe use of dietary supplements containing these ingredients.

Respectfully submitted,



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