July 15, 2019

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD
20993

Docket ID No. FDA-2019-N-1388

RE: Responsible Innovation in Dietary Supplements; Public Meeting; Request for Comments

The Organic & Natural Health Association is a unique national trade organization representing the interests of the dietary supplement supply chain; from raw ingredients, to manufacturers, distributors and brands, retailers and consumers. Our tenets are rooted in the consumer’s demands for transparency, traceability, continual quality improvement and accessibility to the highest quality products available. Demands that have driven industry to voluntarily strive for higher quality, environmental responsibility, and innovation.

Innovation and modernization must be rooted in safety. Fortunately, dietary supplements have an amazing safety record. Researchers found that less than half a percent of reports in a 2 ½ year period qualified as Serious Adverse Events (SAEs)\(^1\). SAEs were found to be predominant in products for weight loss (69.0%) and glycemic control (19.2%) among consumers. In contrast, analysis of the FDA Adverse Drug Event Reporting System 2006-2014 found the number of serious ADEs reported to the FDA increased 2-fold. A total of 902,323 serious outcomes were reported over the 9-year study period: 244,408 deaths, 72,141 disabilities, and 585,774 other serious outcomes. \(^2\)

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\(^2\) J Manag Care Spec Pharm, 2018 Jul;24(7):682-690
O&N agrees that increased effort is required to ensure consumer safety against the egregious producers of illegal products that often contain unapproved drugs or ingredients. Products often marketed for weight loss, energy and sexual performance. Products that are frequently found in convenience stores, at gas stations and on the world wide web. To that end, we want FDA to build on what it has started and efficiently improve enforcement, and will advocate for resources to fully funded enforcement of the existing rules.

Call it a need for innovation or modernization, there is a fundamental, incomprehensible flaw in the definition of health claims vis a vis structure function claims. Dietary supplements are food, and no change in definitions should blur the boundary between supplements and pharmaceuticals. However, it is far too easy to create a new disease. Osteoarthritis, the result of ‘wear and tear,’ is a condition that will impact virtually everyone, and yet, is categorized as a disease. Supplements that can reduce pain may only speak to bone and join health. Structure function claims keep marketing departments busy and consumers confused, while scientific efforts to document effectiveness are discounted.

Existing regulation hogties science to support the impact of supplementation on disease. FDA denied O&N’s health claim petition documenting increased vitamin D serum levels reduce the risk of preterm birth (by 60%), asserting that “as an indicator of vitamin D status, serum levels do not meet the definition of substance. Serum levels are not food or components of food.” It leaves one curious, and slightly outraged, to understand why regulation exists that prevents the correlation of nutrient level to health status. So, is it sufficient to state a supplement is a “dietary substance for use by man,” (or pregnant woman), “to supplement the diet by increasing the total dietary intake?” The statement needs modernization on two counts.

If innovation is defined as the mechanism of creating compounds and products, full disclosure, for the entirely of the supply chain, must be required for ingredients manufactured via the genetic engineering field of synthetic biology. A failure to be 100% transparent completely fails consumers. For example, It is well documented that virtually 100% of canola crops are GMO. Yet, testing of processed foods containing GMO canola often cannot detect this ingredient. The fact that some companies will elect to label a product as having GMO canola, while others with heed the new regulatory exemption and not label, will further confuse the public. In addition, technology is advancing far faster than the pace of the regulatory process. Proposed testing and threshold requirements simply will not work for GMO crops developed with new technology, such as CRISPR and synthetic biology. No company confident in its products should object to disclosing whether it has been genetically edited or grown in a vat of GMO-yeast versus derived from nature. O&N opposes existing GE regulations and is unwilling to support GMO version two.
As for premarket notification and issues relating to New Dietary Ingredients, as noted in our December 12, 2016 comments on FDA’s Revised Draft Guidance for Industry, the NDI notification process, with its objective to ensure product safety, was an admirable goal when the Dietary Supplement Health and Education Act passed in 1994. The practicality of instituting a methodology to address a 22-year delay in defining grandfathered ingredients -- using 1994 as a starting date -- is akin to researching scientific studies using microfiche. It is clear that the level of effort required to create, institute and enforce the proposed NDI Draft Guidance would create additional administrative complexity and hamper innovation with no measurable reward.

Sincerely,

Karen E. Howard  
CEO/Executive Director