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Editorial

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The Regulation of Dietary Supplement in the U.S. and Major Change in the Guidance for New Dietary Ingredient Notifications

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Dietary supplement has become a conservative item on daily menu of Americans. The National Health and Nutrition Examination Survey (NHANES) indicated that one in two Americans take dietary supplement on daily basis.[1] Subsequently, the need of dietary supplement causes the booming of dietary supplement products on U.S. market. According to the Dietary Supplement Label Database (DSLD) of the National Institute of Health (NIH), approximately 50,000 dietary supplement products are currently available on U.S. market.

Here, we want to briefly introduce the dietary supplement related regulations in the U.S., especially the recently proposed dietary ingredient guidance for industry, to help the audience to understand how this type of product is regulated in the U.S. and the important changes in the new guidance.

The U.S. Food and Drug Administration (FDA) regulate both dietary supplement products and dietary ingredients. Dietary supplements are regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA), which is an amendment to Federal Food, Drug, and Cosmetic Act (FD&C). In another word, dietary supplements are regulated under the general umbrella of "food" in the U.S. DSHEA defines dietary supplement as a vitamin, mineral, herbal or other botanical, amino acid, dietary substances, or concentrate, metabolite, constitute, extraction or combination of substances as aforementioned. To help industry better comply with DSHEA, FDA requires dietary supplement manufactures to comply with current good manufacturing practice in manufacturing, packaging, and labeling set forth in Code of Federal Regulation Title 21, Part 111.[2] However, the law does not require the companies to submit the safety evidence of products to FDA, nor obtain FDA's satisfaction that the claim is accurate or truthful before it appears on the product. FDA begins to play a role after the products enter the market. This role is mainly performed by monitoring the serious adverse event report through Safety Reporting Portal, as well as reviewing product labels and other product information. The reporting of adverse events by industry is mandatory, and it is voluntary for consumers and health professionals. FDA take actions to remove products from market only when there are evidences demonstrating adulteration of the product (e.g., containing unsafe ingredients) or/and misbranded (e.g., false labeling), or causing serious adverse effects to human. In the past decade, several fatal events related to dietary supplement (e.g., ephedra) consumption were reported by social media, which raised strong public concerns to the safety of dietary supplements on U.S. market. People criticize the lack of regulation from FDA on dietary supplement products, which is focused on no premarket approval needed to produce and sell this type of products in the U.S.

Compared to the U.S., Canada has relatively more strict regulation to dietary supplements. In Canada, not only the companies are required to obtain license to sell the products on market, but also the products are required to get licensed from Health Canada.[3] And the com-

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panies are required to demonstrate the evidence of safe and efficacy of the products to the government before marketing.

To improve the public understanding and the rate of compliance with the regulation requirements, FDA is making efforts to enhance the safety of dietary supplement products. One of the recent moves of FDA is to revise the outdated draft guidance of new dietary ingredient (NDI) for industry in 2011.

According to DSHEA, the dietary supplement manufactures do not need to get FDA's approval before producing or selling the products unless the product contains a NDI. NDI is defined as a dietary ingredient that was not marketed in the U.S. before October 15, 1994. If the product contains NDI, the industry must submit NDI premarket safety notification to FDA at least 75 days before marketing. However, it is the manufacture itself determines the presence of NDI in their products.

According to FDA's estimate, more than 55,600 dietary supplements exist on the market, and ~5,000 more enter the market each year. However, the agency has received fewer than 1,000 NDI notifications since DSHEA acted in 1994. These numbers, coupled with the concerns about the presence of undeclared active ingredients in the dietary supplements, made FDA to draft a new dietary ingredient guidance for industry in August 2016.[4]

The new NDI guidance aims to help improving public's understanding of NDI notification requirements and improve the quality of NDI notification submitted by companies. For example, it further explains the term "dietary ingredient" in the NDI definition. Dietary ingredient means the ingredient markets in or as a dietary supplement, or for use in a dietary supplement. In other words, the NDI exemption only applies to the ingredients intended to be used in or as a dietary supplement marketed in the U.S. before October 15, 1994. So, if an ingredient used in the food supply chain of a conventional food but not for dietary supplement purpose, it is still considered an NDI even if the product was marketed in the U.S. before October 15, 1994. This new guidance draft is currently under revision, and will be finalized with the considerations of public comments.

Though the new NDI guidance intends to improve the safety of dietary supplements by restricting the definition of NDI and expanding the scope of NDI requires notification to FDA. The arguments will continue because the submission of safety notification is still on a voluntary basis. In the U.S., the law put dietary supplements under the umbrella of "food" regulation, which determines the regulation of dietary supplements is prone to food rather than drug. With more understanding the situation of dietary supplement regulation, the public can read the information of the products better.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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