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MEMORANDUM

From: Martin J. Hahn
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Re: **Dietary Supplement Regulation Update: FDA Announces Public Meeting on Responsible Dietary Supplement Innovation; FDA Launches Dietary Supplement Ingredient Advisory List**

As a part of the Food and Drug Administration's (FDA's) initiative to modernize and reform dietary supplement oversight, 1/ FDA announced it will hold a public meeting on responsible innovation in dietary supplement manufacturing on May 16, 2019. 2/ FDA also recently unveiled a new Dietary Supplement Ingredient Advisory List, a rapid-response tool intended to quickly alert the public when FDA identifies ingredients that do not appear to be lawfully marketed dietary supplements. 3/ FDA has listed four ingredients on the list so far: andarine, higenamine, hordenine, and 1,4-DMAA. This memorandum summarizes these developments.

Public Meeting on Responsible Innovation in Dietary Supplements

FDA will hold a public meeting on responsible dietary supplement innovation to provide an opportunity for stakeholders and the public to present ideas for facilitating innovation in the dietary supplement industry while preserving and strengthening the agency's ability to efficiently and effectively protect the public from unsafe or unlawful products. FDA has also established a public docket to receive comments until July 15, 2019.

FDA explains that the Dietary Supplement Health and Education Act (DSHEA) was intended to regulate a dynamic dietary supplement market with flexibility for innovation. In the 25 years since DSHEA was passed, the dietary supplement industry has grown from a $4 billion market with about 4,000 products to a more than $40 billion market with as many as 80,000 products – if not more.

1/ For a summary of FDA's plans to modernize and reform dietary supplement oversight, *see* FDA Announces Plans for Modernizing and Reforming Dietary Supplement Oversight and Issues Batch of Warning Letters Over Unlawful Alzheimer's Claims, *available at* https://www.hlfoodlaw.com/2019/03/fda-announces-plans-for-modernizing-and-reforming-dietary-supplement-oversight-and-issues-batch-of-warning-letters-over-unlawful-alzheimers-claims/

2/ Responsible Innovation in Dietary Supplements; Public Meeting; Request for Comments, 84 Fed. Reg. 14660 (April 11, 2019).

3/ FDA, Dietary Supplement Ingredient Advisory List, *available at* https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm636081.htm.

However, despite this market growth, FDA only received about 1,200 new dietary ingredient notification (NDIN) submissions since DSHEA was enacted. FDA believes transparency and a common understanding of premarket requirements for dietary supplements, as well as predictable expectations for compliance and consequences for non-compliance, will help FDA's regulatory processes operate more effectively, and that discussion of these issues will help the agency modernize and reform its regulatory oversight of dietary supplements.

In addition, the public meeting announcement contains several proposed topics for discussion and comment:

1. The scope of the phrase "dietary substance for use by man to supplement the diet by increasing the total dietary intake," as used in DSHEA (section 201(ff)(1)(E) of the Federal Food, Drug, and Cosmetic Act);
2. Understanding exceptions to the requirement for premarket notification, and evaluating whether and how growth in the marketplace since 1994 has altered the impact of those provisions;
3. Potential commercial or marketing advantages to incentivize responsible innovation; and
4. Promoting overall compliance with the premarket notification requirement through enforcement.

Dietary Supplement Ingredient Advisory List

FDA recently launched a Dietary Supplement Ingredient Advisory List, which FDA will update when it identifies ingredients that do not appear to be lawfully marketed in dietary supplements. FDA explains consumers may wish to avoid buying and using, and industry may wish to avoid manufacturing or selling, products marketed as dietary supplements containing ingredients on the list. FDA's Deputy Commissioner for Food Policy and Response Frank Yiannis notes that inclusion on the list does not necessarily mean FDA has safety concerns about the ingredient:

> Ingredients will be added to the List following an initial FDA assessment indicating the ingredient may not lawfully be in dietary supplements. This could be for reasons including the ingredient does not fit the definition of a dietary ingredient or the ingredient requires a pre-market notification that was not submitted; however, inclusion of an ingredient on this List is not necessarily an indication of safety concerns. The FDA will continue to communicate separately and clearly any time we identify safety concerns about dietary ingredients or dietary supplements. 4/

Stakeholders are invited to submit information to FDA that may support or refute the agency's preliminary assessment regarding ingredients on the list. Currently, there are four substances included on the list: andarine, higenamine, hordenine, and 1,4-DMAA. Deputy Commissioner Yiannis reinforced that FDA will continue to take action against bad actors who seemingly ignore the legal requirements for dietary supplements, and highlighted 11

4/ FDA Statement from Deputy Commissioner for Food Policy and Response Frank Yiannis on new steps to protect consumers from unlawful ingredients in dietary supplements, April 16, 2019, *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm636132.htm.

recent Warning Letters the agency sent to manufacturers of dietary supplements containing DMHA and phenibut. 5/

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We will continue to monitor FDA's actions to modernize and reform its dietary supplement regulatory framework. If you have any questions on this or any other matter, please contact us.

5/ FDA Acts on Dietary Supplements Containing DMHA and Phenibut, April 16, 2019, *available at* https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm636082.htm.