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

Re: Response to FDA Request for Comment on Revised Draft Guidance on Dietary Supplements, 81 *Fed. Reg.* 53486 (Aug. 12, 2016)
FDA Docket No. 2011-D-0376

Gentlemen:

These comments are filed jointly on behalf of our clients, the Center for Medical Freedom, United States Justice Foundation, The Senior Citizens League, DownsizeDC.org, and Downsize DC Foundation, in response to the Food and Drug Administration's ("FDA") request for comments on its Revised Draft Guidance on Dietary Supplements, 81 *Fed. Reg.* 53486.

Identity of Commenters

The Center for Medical Freedom ("CMF") (www.centerformedicalfreedom.org) is a project of the Conservative Legal Defense and Education Fund, which was founded more than three decades ago, in 1985, as a nonprofit, non-partisan educational organization, incorporated under the laws of Virginia. CMF is tax-exempt under Section 501(c)(3) of the Internal Revenue Code ("IRC"). CMF's mission is to educate members of the public about their right to make their own personal medical and healthcare choices, and their inherent right of self-defense to resist efforts by government at all levels to restrict and control those choices.

The United States Justice Foundation ("USJF"), located in Ramona, California, is a legal defense and educational organization, founded in 1979, and also tax-exempt under IRC Section 501(c)(3). More information about USJF can be found at www.usjf.net.

The Senior Citizens League ("TSCL") (www.tscl.org) is a nonprofit, non-partisan social welfare organization incorporated under the laws of Colorado, and is tax-exempt under IRC Section 501(c)(4). TSCL, headquarted in Alexandria, Virginia, is known as one of the largest U.S. nonprofit and nonpartisan organizations engaging in education and advocacy on

behalf of senior citizens. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned.

TSCL has nearly 1 million senior citizen members and supporters. Its activities include monitoring developments in the United States with respect to the interests of senior citizens and defending those interests before government, developing educational materials designed to explain to senior citizens their various rights as U.S. citizens, raising the level of public awareness of senior citizens' rights by conducting surveys and polls, and publishing and distributing informational newsletters to members, supporters, and the public.

DownsizeDC.org ("DDC") (www.downsizedc.org) and Downsize DC Foundation ("DDCF") (www.zeroaggressionproject.org) are nonprofit organizations, tax-exempt under Sections 501(c)(4) and 501(c)(3), respectively. DDC, founded in 2004, educates both the public and the powerful on the benefits of small government. DDCF launched its Zero Aggression Project in 2015, promoting the principle that it is wrong to initiate force to achieve social or political goals.

Interest of Commenters

Each of these commenters, especially TSCL's members and supporters, as well as all Americans, have a vital interest in ensuring that the Food and Drug Administration follows the law and its regulatory framework allows continued public access to nutritional supplements free of unnecessary government interference. Indeed, TSCL and its supporters are greatly concerned about the impact of all government policies and practices diminishing access to complementary and alternative medicine, and they have special concern for the policies and procedures by which such products might become much more expensive to seniors and others on limited budgets due to the imposition of expensive and unnecessary new regulations.

Background

As part of the **Dietary Supplement Health and Education Act of 1994** ("DSHEA"), Congress defined the term "**dietary supplement**" (21 U.S.C. Section 321(ff)) to include a number of individual products such as vitamins and minerals, as well as such items in "combination." DSHEA adopts the term dietary ingredients to be a subset of dietary supplements. Congress also defined a new term, "**new dietary ingredient**" ("NDI"), as one that "was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994."

After 1994, in order for a dietary supplement to be sold, (i) an NDI must already "have been present in the food supply as an article used for food in a form that has not been chemically altered" or, alternatively, (ii) the NDI's manufacturer must submit to FDA any "information" that forms "the basis on which the manufacturer or distributor has concluded

that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe." 21 U.S.C. Section 350b. If such information is not submitted, then any dietary supplement containing an NDI "shall be deemed to be adulterated" under 21 U.S.C. Section 342(f). In 1997, FDA issued regulations (21 C.F.R. Section 190.6) which generally mirrored the statute, but laid out the requirements for an NDI "notice."

For many years, the dietary supplement industry had little further guidance as to how or what type of information to submit with its NDI notification. Any guidance that FDA may have provided was informal and unpublished.

In January of 2011, the **FDA Food Safety Modernization Act** was enacted, which required the FDA to issue guidance clarifying the NDI notification process. On July 5, 2011, the FDA issued an earlier version of the **Dietary Supplements Draft Guidance**. Then recently, on August 12, 2016, the FDA published a new version of this Guidance ("2016 Draft Guidance"), and asked the public for comment by October 11, 2016. That deadline for comments was extended until December 12, 2016. 81 *Fed. Reg*. 68434.

I. Commenters Support FDA's Move to Ingredient-Specific Rather than Supplement-Specific Notification, But FDA Has Not Gone Far Enough.

The DSHEA speaks in terms of "new dietary **ingredients**" which are used in dietary supplements and which require NDI notification. 21 U.S.C. Section 350b. The FDA's original 2011 Draft Guidance, however, required NDI notification not just for new dietary **ingredients**, but also separately for new **supplements** containing those NDIs. This 2011 Draft Guidance justifiably received criticism from the dietary supplements industry, because the agency had attempted to require a separate NDI notification for **each dietary supplement** even if the ingredients were previously used.

For example, consider a company that previously had submitted an NDI notification with safety information for a supplement containing 100 mg of Ingredient X and 100 mg of Ingredient Y. Under the 2011 Draft Guidance, it appeared to be the FDA's position that an entirely separate NDI notification was needed if the company later wanted to market another supplement containing 150 mg of Ingredient X and 50 mg of Ingredient Y. This created a supplement-specific approach to NDI notifications rather than the ingredient-specific approach, as mandated by the statute.

It would seem that the FDA's **2011 Draft Guidance** met not only with industry criticism, but also was in large measure ignored by the FDA and the industry. According to the FDA's estimates, there are 51,600 **more** supplement products on the market today than there were in 1994, yet the FDA has processed only about 750 NDI notifications during this same period. 2016 Draft Guidance at 12.

In its **2016 Draft Guidance**, the FDA now states that it will "accept notifications that cover multiple dietary supplements and include safety data for a range of doses, daily intake levels, and/or other variations in conditions of use…." *Id.* at 28. Additionally, the FDA will accept a "confidential 'NDI master file'" with "safety information about a range of daily intake levels and/or other conditions of use for dietary supplements containing the NDI." *Id.* at 28, 29. That change would appear to provide welcome relief to the supplements industry.

However, the FDA still claims that a separate NDI notification is necessary — in certain circumstances — including when a product combines the NDI with **additional ingredients** that were not previously indicated, or contains the NDI in **higher dosages** than were covered by the prior notification. 2016 Draft Guidance at 30. This claimed authority appears to be based on the theory that an NDI potentially may be rendered less safe when present in different dosages, or in combination with other ingredients. *Id.*

However, based on the language of the statute, it does not appear that FDA possesses this power to require a separate notice for each new supplement that uses a previously noticed NDI in different potencies and combinations. The FDA's assertion that its power extends to new **supplements** is inconsistent with both the text and the structure of the statute.

First, the statute specifically exempts **old** dietary **ingredients** that were "marketed in the United States before October 15, 1994" — regardless of how they may appear in **new** dietary **supplements**. Thus, the FDA acknowledges that a pre-1994 ingredient "may be used in dietary supplements without submitting an NDI notification to FDA." 2016 Draft Guidance at 16. For example, if Ingredient A and Ingredient B both had been marketed individually before 1994, but a company today wishes to combine them into a single supplement, that new supplement would be exempt from Section 350b. Moreover, if Ingredient A had only been made available in 100 mg dosages prior to 1994, but today a company wants to offer Ingredient A in 1000 mg dosages, it would be exempt from Section 350b's NDI notification requirement. If the FDA — by statute — cannot require separate notifications for each different use of a pre-1994 dietary ingredient, then it would make sense that it cannot require a separate notification every time an NDI is used in a different way.

Second, the NDI notification under the statute requires information showing "that a dietary supplement containing **such dietary ingredient** will reasonably be expected to be safe."[1] As written, the statute requires only that the dietary **ingredient** itself be safe. The language is specific to the particular dietary ingredient, not dietary supplements. The statute creates no requirement that a particular supplement be subject to the same such review.

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[1] FDA, "New Dietary Ingredients in Dietary Supplements — Background for Industry (August 2016) http://www.fda.gov/Food/DietarySupplements/ucm109764.htm (emphasis added).

Otherwise, the statute would have applied to "new dietary supplements" not "new dietary ingredients." The statute simply does not support the FDA's effort to broaden its authority.

In other words, once the FDA has received a sufficient NDI notification for Ingredient X, the FDA cannot then require a separate NDI simply for that ingredient because it will now be combined with other ingredients or used in a different potency. Just because sugar is used for cakes and also for cookies does not mean the **ingredient** is different between the two recipes. And just because the first recipe called for two cups and the new one for three cups does not make the **ingredient** — sugar — new.

It seems clear that Section 350b was never intended to give the FDA the power to impose a requirement that each new dietary supplement obtain what is essentially premarket approval before it can be sold, even though it contains only ingredients for which NDI notifications have already been filed. Under the statute, a "new dietary ingredient" is new only once.

Moreover, interpreting the statute as written does not leave the FDA powerless to protect the public from dietary supplements that could actually be dangerous. Indeed, the FDA has numerous other remedial powers granted by statute. For example, 21 U.S.C. Section 342(f) provides that "A food shall be deemed to be adulterated … if it is a dietary supplement or contains a dietary ingredient that," among other things,

1. "presents a **significant or unreasonable risk of illness or injury** under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use [or]

2. the Secretary declares to pose an **imminent hazard to public health or safety**…."

If the FDA finds a dietary supplement to be adulterated under Section 342(f), then 21 U.S.C. Section 350l(b) gives the FDA the power (if not done voluntarily under Section 350l(a)) to immediately require that distribution of a product be halted, and order all persons in the chain of supply to cease all sales of the product. Further, 21 CFR Section 1.377, *et seq.*, gives the FDA permission to detain articles of food that are adulterated. Additionally, Section 342(f) provides the FDA with a mechanism to "report to a United States attorney a violation … for a civil proceeding." Finally, 21 U.S.C. Section 331(v) makes a prohibited act (with potential criminal penalties under 21 U.S.C. Section 333(a)) "the introduction or delivery for introduction into interstate commerce of a dietary supplement that is **unsafe** under section 350b of this title."

Simply put, the FDA has no health and safety rationale to misread its statutory authority under DSHEA. The FDA has sufficient other enforcement mechanisms to protect the

public from truly unsafe dietary supplements without misapplying Section 350b. Whereas that statute essentially requires "each time you come up with an entirely new substance, we need to know about it in advance," the FDA has transformed that rule into "every time you use a substance in a new way, we need to know about it in advance." By imposing such a requirement, the FDA exceeds its authority. The FDA has no power under Section 350b to require notification when a previously noticed ingredient is simply used in a new product, in a different potency, or combined with different other established ingredients. The FDA may desire to request such power from Congress, but it does not have it. In enacting the DSHEA, Congress sought to preserve access to dietary supplements without undue regulation, so that supplements could continue to be inexpensive alternatives to expensive and often dangerous pharmaceutical drugs.

II. The 2016 Draft Guidance Adopts Positions Entirely Inconsistent with the FDA's Recent Attempt to Remove the Dietary Supplement Vinpocetine from the Market.

The FDA has long-maintained the (widely criticized) position that "a synthetic copy of an herb or other botanical does not qualify as a dietary ingredient," because it "has never been part of an herb or other botanical…." 2016 Draft Guidance at 38. The FDA maintains this position "even if the synthetic copy is chemically identical to a constituent of a plant." *Id.* at 39. At the same time, however, the FDA recognizes that a constituent of an herb or botanical "is an article that is a physical part of a whole, and can be isolated from the whole." *Id.* at 39.

This view is curious, because the FDA recently took the position that Vinpocetine[2] is not a dietary supplement because a synthetic process is used to derive it from an herb or botanical. In other words, unlike the fully synthetic copies that the FDA derides here in the 2016 Draft Guidance, vinpocetine "**has** [] been part of an herb or other botanical," even though it is isolated using a synthetic process. And yet the FDA seeks to remove it from the market.

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[2] Vincamine is a naturally occurring chemical compound found in the leaves of a certain type of periwinkle plant. Through a chemical reaction (dehydration) involving **ethyl alcohol and a catalyst**, Vinpocetine is derived from Vincamine. This is considered a "semisynthetic" process, because the originating material for Vinpocetine is a natural source, and inorganic chemicals are then used to extract a substance that does not exist in nature in that form. This semisynthetic process is to be distinguished from a totally synthetic process where a synthetic substance is created entirely from inorganic ingredients. *See* Comments to the FDA from the Center for Medical Freedom, United States Justice Foundation, The Senior Citizens League, DownsizeDC.org, and Downsize DC Foundation, November 7, 2016, http://lawandfreedom.com/wordpress/wp-content/uploads/2016/11/Comments-on-Vinpocetine-Final.pdf.

Additionally, according to the 2016 Draft Guidance, such synthetic processing should be perfectly acceptable. Indeed, the FDA claims that a dietary supplement has been altered — but note that it is **still considered a dietary supplement** — after "use of solvents other than water or aqueous ethanol … [to] extract[] different types of constituents…." 2016 Draft Guidance at 25. The FDA further explains that an NDI notification is necessary "because the final extract contains only a fractionated subset of the constituent substances in the original dietary ingredient." *Id.* at 21. **But that is exactly how Vinpocetine is produced.** Starting with a plant-based organic compound, a "fractionated subset of the constituent substance" is produced through the "use of solvents."

To be sure, the FDA claims that "some manufacturing changes may alter the identity of the ingredient to the point that it no longer meets the definition of a dietary ingredient." *Id.* at 22. But that was not the reason the FDA gave in its proposal to ban access to Vinpocetine. In other words, the FDA never claimed that Vinpocetine was too chemically distant or dissimilar from Vincamine so as to no longer be considered a dietary ingredient. Instead, the FDA went after Vinpocetine **because** a synthetic process is used to derive it from Vincamine. Yet here, in the 2016 Draft Guidance, the FDA claims that synthetic processes may be used on dietary ingredients, so long as the derivative "has … been a part of an herb or other botanical," and so long as it has not been altered "to the point that it no longer meets the definition of a dietary ingredient."

III. If the FDA Adopts An "Authoritative List" of "Old Dietary Ingredients," It Should Make Clear that It Is Not an Exhaustive List.

For many years, the FDA has refused to recognize any specific dietary ingredients as "pre-1994" ingredients ("Old Dietary Ingredients" or "ODI") that are not subject to NDI notification. In the absence of any official list, the supplement industry has created its own informal lists of ODIs. 2016 Draft Guidance at 19. Now, however, the FDA claims that it is "prepared to develop an authoritative list of pre-DSHEA ingredients, based on independent and verifiable data." *Id.* The industry appears to generally be supportive of this move by FDA.

However, these Commenters are concerned that, if any official list of ODIs is considered a "safe harbor" of sorts, any ingredients that are not included on the list will be presupposed not to be ODIs. This should not be the case. The FDA should make it abundantly clear (and indeed the agency should abide by the principle) that, while inclusion on any "authoritative list" creates a presumption of status as an ODI, the list is not exhaustive, and that non-inclusion of a dietary ingredient does not and should not create any presumption or burden of proof either way as to whether a dietary ingredient is an ODI.

Moreover, publication of an authoritative list of ODIs would make the FDA's current supplement-specific approach (described in Section I, *supra*) even more unworkable. For example, if the FDA includes Ingredient X on a list of ODIs, what if someone wants to combine Ingredient X with Ingredient Y? Is that new supplement still granted safe harbor?

Will the FDA's list contain potency limits for each ODI? This is yet another reason why the FDA should confine its review of NDIs to the limited notification processes described in the statute, and as explained in Section I, *supra*.

Conclusion

The statutory authority of the FDA over nutritional supplements has been carefully circumscribed by Congress, and these limitations must be faithfully adhered to by the FDA.

Sincerely yours,

/s/

Robert J. Olson

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