

July 19, 2022

VIA ELECTRONIC SUBMISSION

Division of Dockets Managements (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1030
Rockville, MD 20852

Re: Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-Market Notification; Draft Guidance for Industry, 87 Fed. Reg. 30843 (May 20, 2022), Docket No. FDA-2022-D-0281

The Consumer Healthcare Products Association (“CHPA”) is the leading national trade association representing manufacturers and distributors of over-the-counter drugs and dietary supplements. Our association is committed to maintaining the highest levels of safety in the manufacture and regulation of dietary supplements and therefore appreciates this opportunity to provide comments on the Food and Drug Administration’s (“FDA” or “Agency”) Draft Guidance, “Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-Market Notification” (“**2022 Draft Guidance**”).

CHPA continues to support FDA’s attention to the “new dietary ingredient” (“NDI”) notification requirement under Section 413 of the Food, Drug and Cosmetic Act. However, we believe that FDA’s issuance of the 2022 Draft Guidance is premature. Instead, FDA’s priority should be on finalizing the 2016 Draft NDI Guidance¹ and clarifying significant unanswered questions about the scope and applicability of the NDI notification requirement. It would be more appropriate for FDA to incorporate its period of amnesty and enforcement discretion policy in a final NDI Guidance, once stakeholders understand the scope of the requirement. Finally, CHPA reminds FDA that enforcement discretion does not alter the bounds of the Food, Drug and Cosmetic Act (“FDCA”) and that NDIs falling in the statutory exemptions are, and remain, outside the NDI notification requirement.

1. CHPA Agrees with FDA that the NDI Notification Requirement Is an Important Tool for Ensuring the Safety of Dietary Supplements

The Dietary Supplement Health and Education Act of 1994 (“DSHEA”)² included multiple provisions that give FDA broad authority to ensure the safety of dietary supplements.³ CHPA agrees with the Agency that the NDI notification requirement described in FDCA Section 413 is important because a “robust NDI notification process represents FDA’s *only* opportunity to

¹ Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry, 81 Fed. Reg. 53486 (Aug. 12, 2016), Docket No. FDA-2011-D-0376 (“**2016 Draft NDI Guidance**”).

² Pub. L. 103-417.

³ See, e.g., FDCA §§ 402(f)(1)(A)-(D).

evaluate the safety of NDIs in dietary supplements before they become available to consumers.”⁴ CHPA also agrees with FDA’s assessment that there are likely a number of NDIs on the market that should have been the subject of an NDI notification prior to marketing.⁵

2. FDA’s Priority Should Be Finalizing the 2016 Draft NDI Guidance

In August 2016, FDA issued the 2016 Draft NDI Guidance—its second draft guidance on the scope of the NDI notification requirement.⁶ CHPA and other industry stakeholders others filed comments on the 2016 Draft NDI Guidance asking FDA for clarification on a number of significant issues that bear on the threshold question of whether the NDI notification requirement applies.⁷

Among other things, CHPA has asked FDA to:

- Establish or acknowledge an authoritative list of “grandfathered” ingredients that were on the market prior to the passage of DSHEA and are therefore not subject to the NDI notification requirement pursuant to FDCA Section 413(d);⁸
- Confirm that, consistent with Congressional intent, pursuant to FDCA Section 201(ff)(1)(E), a dietary supplement can include *any* substance that is intended “for use by man to supplement the diet” including synthetic substances or probiotics, subject to the multiple safety provisions in the statute, including the NDI notification requirement;⁹
- Confirm that, consistent with Congressional intent underpinning FDCA Section 201(ff)(1)(F), a dietary supplement can include a synthetic version of a concentrate, metabolite, constituent, extract, or combination of any ingredient described in FDCA Sections 201(ff)(1)(A)-(E), subject to the multiple safety provisions in the statute, including the NDI notification requirement;¹⁰
- Articulate criteria for evaluating whether processing steps do not “chemically alter” an ingredient for purposes of the FDCA Section 413(a)(1) exemption from the NDI notification requirement;¹¹

⁴ 2022 Draft Guidance at 3 (emphasis added).

⁵ In this regard, it would be helpful for FDA to conduct and share a more rigorous empirical assessment of the number of marketed products that should have been the subject of an NDI notification than is included in the transcript cited by FDA in the 2022 Draft Guidance. *See id.* at 3 & n.3 (citing Transcript, FDA Public Meeting on Responsible Innovation in Dietary Supplements, 180:19–183:4 (May 16, 2019), <https://www.fda.gov/media/127746/download>).

⁶ *See* 2016 Draft Guidance. FDA’s first draft guidance on the scope of the NDI notification requirement was issued in 2011. *See* Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, 76 Fed. Reg. 39111 (July 5, 2011) (“**2011 Draft NDI Guidance**”).

⁷ *See* Comment from Consumer Healthcare Products Association, (December 12, 2016), <https://www.regulations.gov/comment/FDA-2011-D-0376-1986>.

⁸ *Id.* at 5-6.

⁹ *Id.* at 10-11.

¹⁰ *Id.* at 11-12.

¹¹ *Id.* at 13-15.

- Acknowledge that determining that a dietary ingredient is “self-affirmed as [Generally Recognized as Safe (“GRAS”)] for direct addition to food” is a valid alternative to an NDI notification, in a manner parallel to GRAS notifications, as FDA acknowledged in its 2011 Draft NDI Guidance, when a substance has been in the food supply;¹² and
- Confirm an ingredient-focused approach to the NDI notification requirement, consistent with FDCA Section 413(a), rather than a product-focused approach suggested in the 2016 NDI Draft Guidance.¹³

It has been almost 28 years since Congress passed DSHEA and 6 years since FDA issued the 2016 Draft NDI Guidance. Industry still lacks answers from FDA on issues that are fundamental to determining whether the NDI notification requirement applies in a given situation, and if so, what information must be provided. Notably, FDA itself seems to admit that stakeholders currently lack clarity on the NDI notification requirement. In the 2022 Draft Guidance, FDA states: “if you are uncertain as to the regulatory status of your product, you may contact us within the first 90 days of the enforcement discretion period with questions about whether your product is subject to the requirement for premarket notification[.]”¹⁴ In addition, FDA recently stated that it intends to release multiple draft guidance documents as smaller, discreet topics by “finalizing those parts of the guidance that [it] can[,]” including the “NDI Notification Procedures and Timeframes” sections of the 2016 Draft NDI Guidance.¹⁵

Without further clarification of the scope and applicability of the NDI notification requirement in a final NDI Guidance, it simply makes no sense to offer a enforcement discretion for manufacturers to file overdue NDI notifications. FDA’s 2022 Draft Guidance is therefore premature.

3. The Proposed Enforcement Discretion Policy Should Be Included in the Final NDI Guidance

It would be more appropriate for FDA to announce a period of enforcement discretion at the time the 2016 Draft NDI Guidance becomes final. At that point, FDA will have clarified its position on the remaining outstanding issues, including those identified above. Manufacturers and distributors will then have clarity on FDA’s expectations and on the dietary ingredients that *should have* been the subject of an NDI notification prior to marketing. A period of 180 day enforcement discretion at that time will allow those manufacturers and distributors to assemble the requisite information and file a comprehensive NDI notification that will add to FDA’s insight into the safety of the ingredient, as intended by the statute.

4. Statutory Exemptions Are Not Affected by Any Enforcement Discretion Policy

¹² *Id.* at 15-16.

¹³ *Id.* at 18-22.

¹⁴ 2022 Draft Guidance, at 6.

¹⁵ Daniells, S., *FDA Working “Expediently” to Finalize NDI Draft Guidance Sections*, NutraIngredients-USA (June 13, 2022), <https://www.nutraingredients-usa.com/Article/2022/06/13/FDA-working-expeditiously-to-finalize-NDI-draft-guidance-sections> (comments by Betsy Jean Yakes, Ph.D., Acting Director of FDA’s Division of Research & Evaluation, and an unnamed FDA spokesperson).

Under DSHEA, a premarket submission of safety data is required for an NDI if it is not subject to either of two statutory exemptions. The first statutory exemption applies to dietary ingredients that were marketed in the United States prior to October 15, 1994.¹⁶ The second statutory exemption applies to those dietary ingredients that are “present in the food supply as an article used for food in a form in which the food has not been chemically altered.”¹⁷

We note that many of our member manufacturers and distributors have engaged in thorough analyses of their dietary ingredients to assess whether they fall into either of these statutory exemptions. In addition, they ensure that products generally meet all safety requirement established by the FDCA, including:

- FDCA Section 402(f)(1)(A), which states that a dietary supplement or dietary ingredient will be considered adulterated if it “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;” and
- FDCA Section 402(f)(1)(B), which adds that a dietary supplement or dietary ingredient will be considered adulterated if it “is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury[.]”

These manufacturers and distributors have relied on these analyses to bring safe and suitable dietary supplement products to market.

CHPA reminds FDA that the law regarding the statutory exemptions has not changed. Therefore, no matter the timing of an enforcement discretion policy, stakeholders are entitled to rely on their analyses of the exemptions to the NDI notification requirement. CHPA would like FDA to confirm that this is the case, and that this enforcement discretion initiative is not an attempt to generate NDI notifications for pre-DSHEA or NDI-exempt substances.

Best Regards,



Douglas MacKay, ND
Senior Vice President, Dietary Supplements
Consumer Healthcare Products Association
dmackay@chpa.org

¹⁶ FDCA § 413(d).

¹⁷ *Id.* § 413(a)(1).