

DSHEA 2.0
Legislative Reforms
Addressing Deficiencies in the
Dietary Supplement Marketplace

<u>The Problem</u>	<u>The Cause</u>	<u>The Solution</u>
<i>Undefined Marketplace Prevents FDA from Identifying & Adequately Assessing Products and Ingredients for Safety</i>		
<p>FDA does not know what products are being marketed</p>	<ul style="list-style-type: none"> • Supplements are often introduced and sold without FDA knowledge or the knowledge of state regulators & consumer advocates 	<ul style="list-style-type: none"> • Require that manufacturers list all products in a publicly accessible FDA database, including the following information: <ul style="list-style-type: none"> ○ All information on the supplement’s label ○ All Structure/function claims found in the labeling and marketing of the product ○ Summary of evidence used to substantiate structure/function claims ○ Enforcement actions, public notices, reports (<i>e.g.</i>, warning letters, recalls, alerts, inspection reports) ○ Known significant adverse event data ○ “Pathway” to market (<i>e.g.</i>, NDIN, GRAS, GRAS self-affirmation, prior use) ○ Summary of evidence establishing safety for GRAS Self-affirmation
<p>New dietary ingredients (“NDIs”) are sold without FDA knowledge or safety review</p>	<ul style="list-style-type: none"> • Companies can secretly self-affirm and market new dietary ingredients and uses as “Generally Recognized as Safe” (<i>i.e.</i>, “GRAS” loophole) in foods and then introduce them into dietary supplements without FDA knowledge • Companies fail to correctly identify dietary ingredients and uses as “New Dietary Ingredients” 	<ul style="list-style-type: none"> • Prevent companies from using GRAS for dietary ingredients • More clearly define “NDI” <i>via</i> directed rulemaking or guidance • Create a timeline for companies to submit NDI Notifications (“NDINs”) for substances currently marketed without NDIN review • Require companies to include “pathways” to market (<i>e.g.</i>, NDIN, GRAS, GRAS self-affirmation, prior use) in their product listing • Summary of evidence establishing safety for GRAS Self-affirmation

<i>Ineffectual Regulation of New, Novel, and Non-dietary Ingredients</i>		
New Dietary Ingredients are introduced without data needed to assess safety	<ul style="list-style-type: none"> FDA’s draft NDIN guidance was never finalized 	<ul style="list-style-type: none"> Direct FDA to strengthen and finalize NDIN guidance
Hundreds of illegal CBD supplements are on the market	<ul style="list-style-type: none"> Despite FDA’s express prohibition of CBD use in foods and dietary supplements, enforcement has been weak 	<ul style="list-style-type: none"> Direct FDA to prioritize enforcement and publish a long-term comprehensive plan for CBD and other cannabinoids in food, supplements, drugs, and cosmetics Within 5 years, submit a report to Congress on the current state of the CBD dietary supplement marketplace and the status of FDA’s regulations/oversight.
Dangerous products can fall between the regulatory “cracks” (e.g., pure tianeptine or phenibut)	<ul style="list-style-type: none"> Supplements containing only non-dietary ingredients cannot be regulated as dietary supplements even if they are marketed as such 	<ul style="list-style-type: none"> Modify the definition of adulterated/misbranded supplements to include all products marketed as supplements or like supplements that do not contain a dietary ingredient
<i>Supplements can be Dangerous and Contain Undeclared Contaminants</i>		
Certain categories of supplements are particularly subject to tainting	<ul style="list-style-type: none"> Weight loss, performance-enhancing, sexual enhancement, and cognitive supplements are notable bad actors 	<ul style="list-style-type: none"> Require additional testing and prioritize inspections for high-risk supplement categories
Inability to act expeditiously against supplements adulterated with prescription drugs	<ul style="list-style-type: none"> FDA does not have mandatory recall authority over prescription drugs 	<ul style="list-style-type: none"> Grant FDA recall authority over supplements adulterated with prescription drugs
FDA has difficulty removing products with dangerous ingredients from the market	<ul style="list-style-type: none"> The adulteration standard is too high: <ul style="list-style-type: none"> “significant or unreasonable risk of illness or injury...under the conditions of use recommended or suggested in labeling” (21 USC § 342(f)(1)(A)) 	<ul style="list-style-type: none"> The adulteration standard should be similar to the NDIN standard <ul style="list-style-type: none"> <i>i.e.</i>, A product should be considered adulterated when the supplement: <ul style="list-style-type: none"> cannot <i>reasonably be expected to be safe</i> (the current NDIN standard <i>under</i> 21 U.S. Code § 350b) [Alternatively] <i>can no longer reasonably be certain of no harm</i> (our recommended NDIN standard)
Product dangers are underreported	<ul style="list-style-type: none"> Industry is currently obligated to only report serious adverse events they receive from consumers to the FDA Consumers lack adequate information about how to report adverse reactions 	<ul style="list-style-type: none"> Require manufacturer reporting of all adverse events Require supplement labels and online listings to include phone numbers and links to FDA reporting systems
The Problem	The Cause	The Solution

Supplements May Make Unsubstantiated Claims

<p>Supplements often make illegal and unsubstantiated structure/function claims</p>	<ul style="list-style-type: none"> • The FDA does not have the resources to monitor the market for the thousands of claims made by supplement companies. 	<ul style="list-style-type: none"> • Require dietary supplement companies to list in a public FDA database all structure/function claims • Require companies to summarize data used to substantiate the claims
<p align="center"><i>Weak Enforcement</i></p>		
<p>FDA cannot keep up with marketplace growth, including increasing online sales</p>	<ul style="list-style-type: none"> • The former \$4 billion industry comprised of about 4,000 unique products is now an industry worth more than \$40 billion, with over 50,000 products • The budget for FDA’s Office of Dietary Supplements Programs has not kept pace with industry growth and is currently only about \$11 million 	<ul style="list-style-type: none"> • Provide Office of Dietary Supplement and Programs (ODSP) with \$10 million in additional funds to improve its oversight and enforcement • Allow state attorneys general to pursue civil enforcement for violations of DSHEA in their jurisdictions • Require enforcement activity (warning letters, test results) to be cross-referenced in the FDA database to facilitate public access
<p>FDA enforcement actions do not deter bad actors and manufacturers can rebrand/reformulate their products or start a new company to evade enforcement.</p>	<ul style="list-style-type: none"> • FDA can send warning letters or pursue criminal penalties, but warning letters are often insufficient and criminal penalties are rarely pursued. • FDA cannot consider whether a company has rebranded/reformulated its supplement or created a new company to evade enforcement. 	<ul style="list-style-type: none"> • Authorize FDA to administer civil penalties against individuals and companies for violating DSHEA. • Provide FDA discretion in setting penalties to take into account the nature, circumstances, extent, and gravity of the violations and any history of prior violations.
<p>Quality control issues (e.g., <i>Salmonella</i> in kratom, contaminated products)</p>	<ul style="list-style-type: none"> • Lack of safety oversight/process controls 	<p>Provide Office of Dietary Supplement and Programs (ODSP) with \$10 million in additional funds to the to improve its oversight and enforcement</p>