Modernizing and Strengthening Policies to Advance the Safety and Quality of Products Marketed as Dietary Supplements

The Dietary Supplements Quality Collaborative (Collaborative, or DSQC)[1] supports policies and resources to advance innovation; help ensure safe, quality supplements; remove illegal and tainted products from the marketplace; and promote consumer education.

Millions of consumers use dietary supplements in an effort to maintain health and address shortfalls in their dietary intake. Companies that fail to comply with current Good Manufacturing Practice (CGMP) regulations, and those that illegally market products containing unlawful ingredients, should be held accountable.[2]

We endorse the following recommendations to help promote supplement safety, advance transparency, and embrace quality.

I. PROMOTE SAFETY

All stakeholders benefit from a regulatory framework that promotes product safety and provides appropriate tools and resources for the U.S. Food and Drug Administration (Agency, or FDA) to maintain appropriate oversight that promotes safety.

- **Strengthen and clarify FDA's authority over products illegally marketed as dietary supplements that are adulterated with drugs or drug analogues.** The DSQC supports appropriate enforcement tools and policies, which may include mandatory recall and related authorities over products that are marketed as dietary supplements, but contain drugs or drug analogues.
- **Utilize risk-based inspections.** We support FDA's use of a risk-based approach toward prioritizing inspections for dietary supplement facilities. Factors that may impact risk include: specific products often associated with quality or safety issues; probability of risk occurrence and severity of impact; a company's history of current Good Manufacturing Practice (CGMP) problems; and whether and when a company has been audited by a qualified third-party auditor.
- **Strengthen existing adverse event reporting systems.** We support greater interoperability across Federal government sites to collect, store, access, and share information regarding serious adverse events involving dietary supplements.
- **Support FDA's efforts to evaluate the safety of supplement products and ingredients through collaborative research and shared understanding.** As a specific example, we support the Agency's recent creation of the Botanical Safety Consortium, a public-private partnership that will explore cutting edge toxicology tools.

II. ADVANCE TRANSPARENCY

The Collaborative endorses and encourages the adoption of leading industry approaches[3] to help ensure increased transparency among manufacturers, regulators, and the public.

- **Require listing of marketed dietary supplement products.** Current law does not authorize FDA to require companies to submit product information (listing) about marketed dietary supplement products, limiting FDA's knowledge about these products, their ingredients, and who manufactures them. The Collaborative supports legislation that would require product listing for dietary supplements to enhance transparency in the marketplace and help identify products and constituents that may put the public at risk and undermine consumer confidence.
- **Explore mechanisms to provide additional information on product labels.** As part of promoting responsible innovation, FDA, industry, and other stakeholders should explore ways to include additional information on product labels to better inform health care providers and consumers about supplements, including more transparency around the ingredients in proprietary blends; advisory statements regarding potential interactions; risks associated with overuse and special populations; and approaches to ensuring accurate and useful disclosure of ingredient measurement (e.g., probiotics and overages).

III. EMBRACE QUALITY MECHANISMS

All stakeholders benefit from a regulatory framework that helps promote safe, quality supplement products.

- **Support efforts by both FDA and industry to increase manufacturer awareness of CGMP regulations and public standards for quality.** We support educational efforts to encourage manufacturer and distributor compliance with CGMP regulations, including quality control operations and the establishment of specifications for the identity, purity, strength, and composition of finished dietary supplements and their ingredients.
- **Encourage industry efforts.** We support enhancing industry efforts to qualify and validate ingredient suppliers; promote a secure supply chain; appropriately test ingredients and finished products; and identify and remove products that pose safety concerns from the market, including fostering retailer/manufacturer due diligence.
- **Build consumer trust through educational efforts.** The Collaborative supports efforts to increase consumer, healthcare practitioner, and retailer awareness of resources to help consumers select quality supplements, including educational efforts to build label literacy.

REFERENCES

1. The Collaborative, dsqcollaborative.org, is an organization committed to the advancement of policies and initiatives designed to help ensure the quality and safety of products marketed as dietary supplements in the U.S. market. Our members and observers represent consumer organizations, dietary ingredient and dietary supplement manufacturers, public health and patient advocacy groups, health care providers, standard setting organizations, non-profit organizations, and academia.
2. See the Collaborative's Paper on Products Illegally Marketed as Dietary Supplements and Proposed Multi-Stakeholder Responses: dsqcollaborative.org/sites/default/files/dsqc/PDF/dsqc_tainted_products_briefing_document.pdf.
3. E.g., The Supplement OWL, Online Wellness Library, supplementowl.org.