

The Modernization of Dietary Supplement Regulation: the Botanical Safety Consortium

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FDA's Office of Dietary Supplement Programs

- Directs FDA's dietary supplement activities
 - Provides policy perspective
 - Reviews dietary supplement & ingredient safety
 - Processes CGMP, misbranding, disease claim compliance actions
 - Expertise for civil and criminal cases
- ODSP Priorities
 - Protect consumers
 - Ensure product integrity
 - Promote informed decision-making

Dietary Supplement Modernization

- FDA Commissioner Statement, February 2019
- Highlights
 - Enhanced communication
 - Commitment to enforcement
 - Flexible regulatory framework
 - Engage in a public dialogue
 - Partnering to protect public health



Dietary Supplement Ingredient Advisories

“...new ways to communicate more quickly when we have concerns that an ingredient is unlawful and potentially dangerous and should not be marketed in dietary supplements...”

- Feb 2019 Statement

Dietary Supplement Ingredient Advisories

- Rapid response tool
- Faster communication of concerns to the public
- Preliminary assessment
- Opportunity for stakeholders to share information

Enforcement and Other Activity

“...we’ll continue to take actions to protect public health ... and develop new enforcement strategies, as a key element of our approach to protecting consumers as the risks evolve...”

- Feb 2019 statement

Enforcement and Other Activity

- Claims-specific compliance actions
- Ingredient-specific compliance actions
- Judicial actions
- Safety alerts

Responsible Innovation in Dietary Supplements

“...need to ensure that our regulatory framework is flexible enough to adequately evaluate product safety while promoting innovation...”

- Feb 2019 statement

Responsible Innovation in Dietary Supplements

- Public Meeting, May 2019
 - Discussion of permissible dietary ingredients within section 201(ff) of the FD&C Act
 - Issues related to when an NDI notification might not be required
 - Challenges and opportunities associated with promoting compliance with the NDI notification requirement
- Stakeholder discussions
 - Master files
 - ODI list

Legislative Proposal to Modernize DSHEA

“...we’ll engage a public dialogue around whether additional steps to modernize DSHEA are necessary. . . We believe there may be opportunities to modernize DSHEA for the future, while preserving the law’s essential balance...”

- Feb 2019 statement

Legislative Proposal to Modernize DSHEA

- Engaging in a public discussion
- Mandatory Product Listing
 - Improve transparency
 - Strategic use of FDA's resources
 - Risk-based approach to research and inspections
 - Level the playing field for responsible industry
- Drug exclusion loophole

Botanical Safety Consortium

“...it’s critical that the FDA continue to work closely with our partners in industry to achieve our primary goal of protecting public health and safety...”
- Feb 2019 statement

Botanical Safety Consortium: Science to Inform Decision-Making

- The consortium was formally convened, Nov 2019
 - FDA, NIEHS, and HESI executed the MOU
 - Collaboration between government, industry, academia, and elsewhere
- Generate a sound scientific basis for integrating existing safety data and the latest toxicology tools to evaluate botanical safety

Botanical Safety Consortium: Science to Inform Decision-Making

- Important to FDA's regulation of dietary supplements
 - Not a direct link to regulatory decisions
 - Allows FDA to leverage existing resources to evaluate products
- Important to responsible firms evaluating the safety of potential new products

Thank you

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