DS Regulatory Summit, Regulatory Reform: Industry's Top Ideas for Change

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DSHEA

Need for clarification and regulatory definitions to reduce burden

1. Demarcation of Old Dietary Ingredient and New Dietary Ingredient
   - Post Public Meeting
     1. FDA resources
     2. Industry documentation of ODI
     3. Manufacturing process changes
   - Potential solution:
     - "Negative List"

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Negative list

Examples include:

- BMPEA
- Bulk powdered and liquid caffeine
- Kratom
- DMAA
- Ephedra

Refocus on the goals of ODI list

- Safety
  - **Synthetic** copies of botanicals should go through the notification process
  - **MFG change**: for example it should not be “what was the manufacturing technique for echinacea in 1994”?
- Prohibited ingredients (unsafe or with unknown history)
- Increase rate and quality of NDI notifications
- UNPA members compliance goal

FSMA

Need for clarification and regulatory definitions to reduce burden including:

1. *Produce Rule*
   - Ag water, “farm” definition, produce not covered list
2. *Preventive Controls for Human Food*
   - Dietary supplement (DS) exemption language
   - Modifications for DS confusing
   - Responsibilities of a retail brand and the “it depends” products
   - Critical limit not defined
   - Record retention: two years conflicts with FSP review every three years

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3. *Foreign Supplier Verification Programs*
   - Why DUNS number?
   - Why different definition for Qualified Individual for PC vs FSVP?
   - Modifications groups seem confusing (label and component spec.)
   - FSVP Importer expectations do not match current business practices for supply chain communications
     - Written assurances (supplier and customer)
     - Information transfer through a broker or distributor is not easy
     - Does not address the business model of “two men and a phone in N.J.”

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Thank you!

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