

New Dietary Ingredients: Enforcement

NDIs & the New Political Reality: What to Expect in the Post Regulatory Age

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Enforcing NDI Policy

1. What are FDA priorities?
2. FDA enforcement strategies
3. Enforcement trending

Priorities

1. Safe products

- Pre-market review
- Post-market surveillance
- Mission oriented research

2. Product identity, integrity*, and quality

- GMP inspection/enforcement
- Product sampling and testing

*Integrity: meets supplement facts label claim with nothing more

Priorities

Food Safety Modernization Act (FSMA) Dietary Supplements

1) **Hidden or intentionally adulterated products**

- “FDA has a history of taking legal action against supplement makers who include hidden or deceptively labeled ingredients in their products. These could be potentially dangerous to consumers, especially those using medications or with health condition.”

2) **NDI with unknown safety profile**

- “...manufacturers must notify the agency in advance when adding a new ingredient with an unknown safety profile to their products. The manufacturer must also provide evidence that the ingredient is safe for consumers.”

FDA Enforcement Tools

Voluntary Compliance

- Administrative action:
- Inspection and reporting
- Issuing guidelines and regulations
- Warning letters
- Publicity

Civil and Criminal Penalties

- Seizure
- Injunction
- Civil Money Penalties
- Prosecution

Import Alert

- “may render unhealthy”
- Burden of proof = “appears”
- Refusing entry
- Allowing reconditioning

Enforcement Strategies

- FDA Investigator via inspection
- Import Operations
- Label Review
- Ingredient on the “radar”
- Complaints

Regulatory Action for NDI Warning Letters

- **Androstenedione**
 - March 2004, 23 WLs
 - December 2004 WL to Pennsylvania firm

- **1,3- dimethylamylamine HCl (DMAA)**
 - April 2012
 - July 2013, 11 WLs

Regulatory Action for NDI Warning Letters

DMBA

(AKA including Dimethylbutylamine)

- April 2015, WL to 14 companies, 17 products
- September 24, 2015
- March 31, 2016

Regulatory Action for NDI Warning Letters

2015

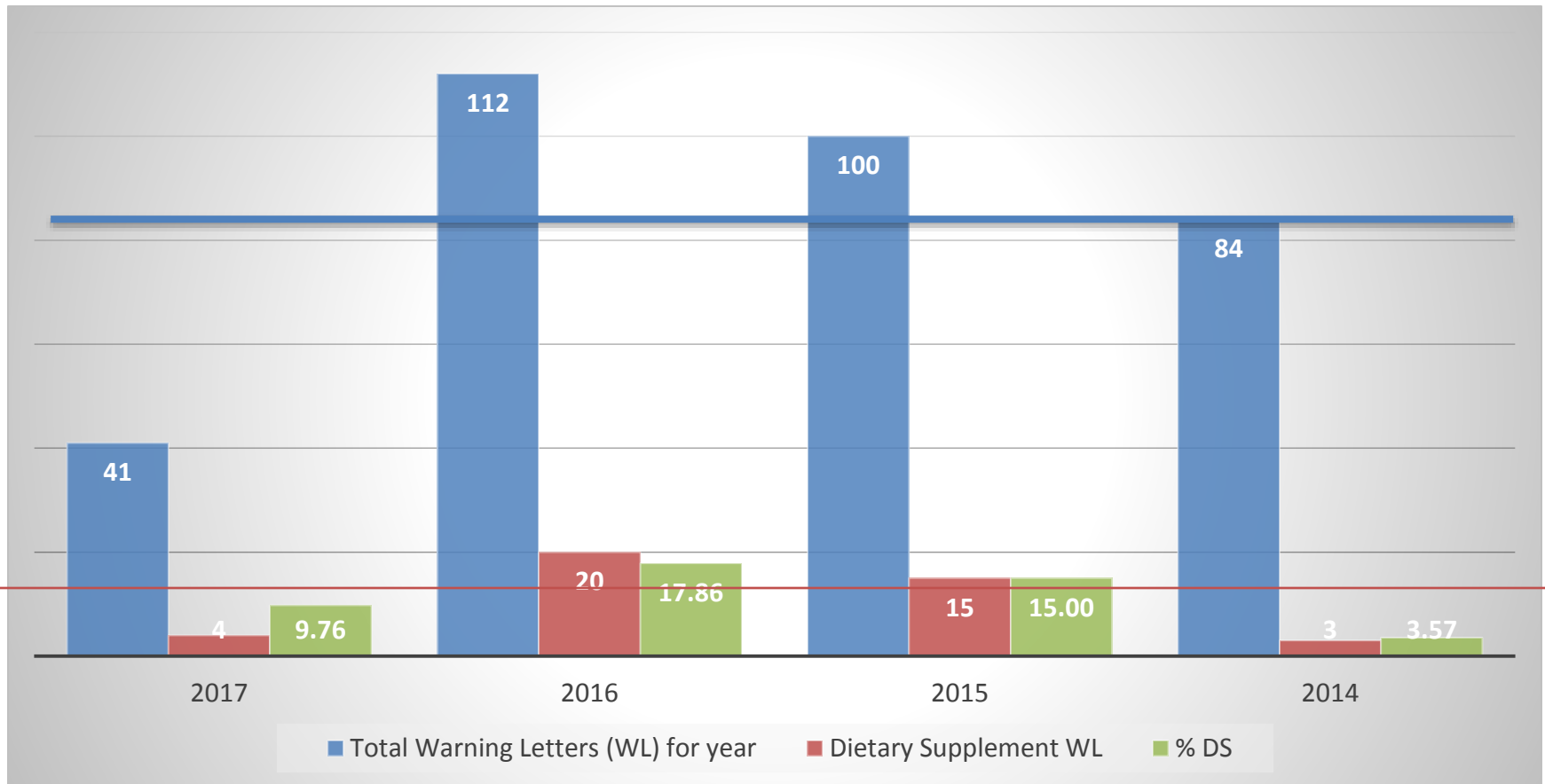
- **BMPEA** (Beta-methylphenethylamine)
 - 5 WL, April 2015
- **Bitter Orange**
 - WL Sept 2015
- **Picamilon**
 - 5 WL, November 2015

2016

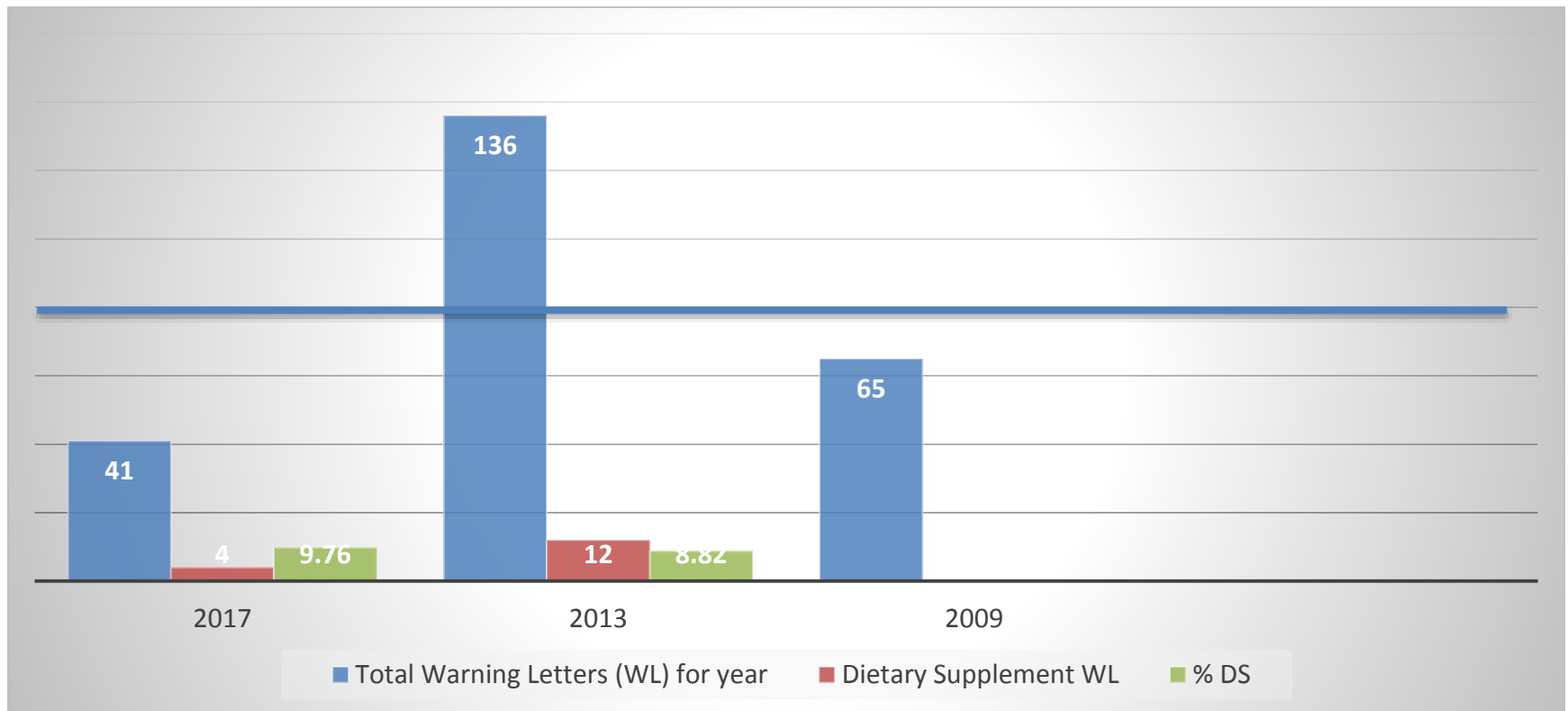
- **Kratom**
 - WL, December 2014 to a Tampa, FL firm
 - 15 domestic seizures, January 2016
 - Import Alert, December 2016
- **Methyl Synephrine**
 - 7 WL March 2016

Warning Letters

issued year to year from January 1 to March 2



Warning Letters issued during inauguration years January 1 to March 1





Thank you!

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