

# New Dietary Ingredients (NDI)

▶ **THEY'RE HERE!**

# New Dietary Ingredients (NDI)

- ▶ Guidance is still "pending"
  - ▶ Still forecasted to be finalized by the end of the year
  - ▶ May NOT be affected by the regulation "roll-back"
  - ▶ New Label Guidelines may be this issue FDA targets for change/roll-back.
  - ▶ Guidance interprets regulation already in place

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- ▶ FDA is determined to enforce NDI regardless of the finalization of the "Guidance".
- ▶ Agency is directing those registering to follow the guidance "if they wish".
- ▶ Most of the current action is around ingredients
- ▶ FDA has seen an increase (28%) increase in notifications so far in 2017 compared to 2016.

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- ▶ FDA has seen the increase go from 4-5 per month to 6-8 per month
- ▶ The ratio of "No-Objection versus Objection Response letters is 1:4
- ▶ Main reason for "Objections"
  - ▶ Proving "History of Use"
  - ▶ Demonstrating reasonable expectation of safety.

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- ▶ History of Use:
  - ▶ Poor or no documentation of past use
  - ▶ "Traditional Usage" does not qualify
    - ▶ Must be documented "past use"
    - ▶ Preferably in US but will "look" at usage in other countries.
  - ▶ Ads, receipts, menus, other "written copy" in order to have a chance.

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- ▶ Expectation of Safety:
  - ▶ Studies:
    - ▶ 14 Day
    - ▶ 90 Day Tox
    - ▶ LD 50
  - ▶ Cannot use "history of use" in AER program

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- ▶ Enforcement
  - ▶ Internet search of labels for ingredients
  - ▶ Comparing to "Grandfather/Safe Harbor" lists (not official) which contain approximately 2000 ingredients
- ▶ May spur additional regulatory action

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- ▶ Solutions:

- ▶ Examine your formulas
- ▶ Does a "core product" depend on a potential NDI
- ▶ Establish a "Master Substantiation File" for ingredients and product formulas
  - ▶ MSF should contain all information required for NDI notification of ingredient.
  - ▶ Stay away from submitting FG formulas and focus on ingredients

Submit notification to FDA.

Enlist "expert" help or services to assist in this process

FDA is currently NOT asking how long you have been using the ingredient in your product.