

**Initial Comments Regarding the FDA's
Draft Guidance Document on New Dietary Ingredients**

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For years those who fight for health freedom have been fighting the use of government regulations to suppress the free market system and personal choice. This regulatory creep snipping away at liberty is no longer just our issue. In the last few years, Congress and the Administration have passed massive bills with long reaching consequences in numerous industries. From banking to food and health insurance, Congress has dramatically expanded the regulatory powers of the federal government far beyond what was intended by our Founders.

Add to this that the Administration has gone even further than Congress and is pushing new regulations on numerous industries through the administrative rulemaking process as well the latest strategy illustrated by the Food and Drug Administration (FDA). In July the FDA released a draft guidance document on New Dietary Ingredients which follows the latest government 'rulemaking by guidance document' strategy. A strategy that is impermissible under federal law.

The deleterious effects of this are so far reaching that legislation entitled "Regulation Moratorium Act of 2011" (H.R.1235 and S. 1531) has been introduced in both the House and Senate to prohibit most federal rulemakings until January 31, 2013.

A Snapshot of the Facts on the FDA's NDI Draft Guidance Document:

What: A draft document entitled, "Guidance for Industry, Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" was published by the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition in July 2011. (FDA Docket No: 2011-D-0376).

Initially the deadline for response was 90 days, but after many calls for an extension, the deadline for response was extended to December 2, 2011.

Why: The FDA Food Safety Modernization Act (Public Law No. 111-353) required the agency to publish within 180 days additional guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient. The law states:

"(b) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identify of a new dietary ingredient"

Why Did Congress Put This Language In: *Because the industry asked them to!* Sadly, the industry and its trade associations and lawyers fell into a trap set by the FDA. (Can we say ephedra déjà vu all over again?) The FDA issued a rule making on NDIs in 1997, but some thought it insufficient. Add to the mix the failure of the agency to act on companies who marketed anabolic steroids as dietary supplements without submitting NDI notices (thus making them adulterated) in the middle of a media frenzy and 'something' had to be done. Keep in mind, the FDA failed to respond to questions on steroids in supplements for years until Senator Orrin Hatch stated publicly that he considered these ingredients not to be dietary supplements.

Responses So Far: As of mid-October there are 83 comments in the docket. This number is misleading because form letters are not counted individually. One form letter has more than 6,000 submissions. Another has 300+. Three or four others likely have 500 additional letters. Of the 83 comments, there are only two that are substantive. The FDA needs specific instructions and edits to utilize in their redraft. Most of the public comments are from health professionals and private citizens telling the FDA they have 'gotten in wrong'. In fact, 100% of the letters to date oppose the NDI as written. None of the trade associations or companies have as yet submitted their comments. That the document is 86 pages with more than 50 attachments, is a key reason for the delay in comments.

Ways to Submit Comments:

All comments should reference the docket number (FDA-2011-D-0376-0079)

Submit electronic comments to <http://www.regulations.gov>
(You can submit as an attachment which will come up as a PDF.)

Mail comments to: Division of Dockets Management (HFA-305)
 Food and Drug Administration
 5630 Fishers Lane, Rm. 1061,
 Rockville, MD 20852

Observations in Reviewing the Draft Guidance Document:

The FDA has acknowledged (approved) 164 and rejected 450 of the 700 NDI notifications submitted since 1994.

DSHEA Instruction: October 25 marks the 17th anniversary of the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) which became Public Law No: 103-417. Congress, in crafting this law stated: **(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers.**

Problems with the FDA's Draft Guidance Document:

- 1. The FDA is attempting 'Rulemaking by Guidance' which is not permissible.**
 - A. The FDA states officially that the Guideline once finalized will not be 'binding' meaning they do not carry the official power of regulations. However this is incorrect in so much as the 'current thinking' presented in this document is far different than the existing NDI regulation and the laws on the books.
 - B. The FDA has set the stage to implement *de facto* new regulations.
 - C. This guidance document if finalized as drafted would become the framework by which the agency operates and expects the industry to operate.

- 2. The FDA is attempting to create significant new burdens on industry.**
 - A. The FDA places the responsibility for presenting an alternative method of validating an NDI on the shoulders of the submitter (manufacturer or distributor).
 - B. This guideline if implemented as drafted will create many barriers for innovations in the industry in particular for smaller companies with fewer resources to fight protracted legal battles with the federal government.
 - C. The agency is suggesting that BOTH dietary supplement bulk ingredient providers and distributors would need to submit NDI notifications.
 - D. The information requested far exceeds what was initially requested in the 1997 regulation, going so far as to ask for production details not just evidence of safety. This is moving dietary supplement documentation requirements more towards a drug model, which is clearly not what Congress intended and not necessary.

- 3. The FDA's entire premise is fatally flawed**
 - A. The FDA is proposing that instead of submitting an NDI notification on a dietary ingredient (one time by one company) that an NDI notification will likely be needed for every product in which the NDI is included, if the ingredients are different from product to product, or the target consumer population is different.
 - B. The FDA attempts to focus only on the definition of a New Dietary Ingredient rather than the entire descriptive paragraph put forward into law by Congress. Meaning a dietary ingredient in a food which may have been consumed for millennia but which has not been marketed as a supplement would be considered an NDI and thus a costly NDI notification process may be required.
 - C. The FDA only considers the US marketplace as valid in their consideration. This is not what Congress stated or intended. There are many foods from around the world which may or may not have been marketed in the United States. It is discriminatory to exclude legitimate food sources from other countries.
 - D. The FDA conflicts itself in numerous sections within the document in stating whether or not an NDI notification should be submitted.

4. Some Existing Products Could Become Targets

- A. Products containing ingredients which were in the food supply, but not in dietary supplements may be at risk for an adulteration notification.
- B. Products containing ingredients marketed in supplements outside the United States, but not in the US may be at risk for an adulteration notification.
- C. Probiotic products are particularly vulnerable.
- D. Synthetic ingredients are targeted for elimination as dietary ingredients.
- E. Products that utilize Nanotechnology could be barred.

5. Manufacturing Process Innovation Could Trigger NDI Notification Requirement.

- A. If this guidance is implemented, changes in manufacturing procedures trigger the need for an NDI Notice.
- B. The FDA suggests that even using a different part of a plant will require an NDI notification.
- C. Heating up the ingredients could require an NDI notification.
- D. Changing the agricultural or fermentation conditions of the ingredients (such as sprouting or using a medium such as sodium selenite) could trigger an NDI notification requirement.
- E. Using the plant at a different stage of maturation could trigger an NDI notification requirement.

6. Drug Research Make Keep Products Out of Dietary Supplements.

- A. The FDA suggests that a Citizens Petition would be required to market a dietary ingredient that has been part of a drug development program but is no longer being studied.
- B. The current thinking is that an article that has been authorized for investigation as a new drug or as a biologic before being marketed as a food or dietary supplement cannot be marketed as a dietary supplement if substantial clinical investigations of the article have begun and the existence of such investigations have been made public.
- C. A dietary ingredient could be barred from being marketed as a dietary supplement if the drug industry is researching a component of the ingredient as an investigational new drug under IND.

7. The FDA has set the stage for a shift to pre-market approval (i.e. drug model regulations).

- A. Throughout the draft guidance document, the FDA is setting the stage to pull the dietary supplement regulations closer to the drug regulations model.
- B. The NDI notification procedures outlined and offered form create a situation that bears a striking resemblance to the billion dollar drug pre-market approval process.

Conclusion:

This guidance document if finalized as written will have a number of far-reaching effects on industry and the marketplace. Consumers are not well served by the resulting higher prices and reduction in some products in the market that surely will follow if industry is forced to comply with these overburden some proposed procedures.

This proposed new dietary supplement notification process is fatally flawed, contrary to law and should be immediately withdrawn and revised so that it is consistent with the existing regulation, and both the spirit and letter of the law.

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