

NEW DIETARY INGREDIENTS AND FOOD ADDITIVES: WHAT THEY HAVE IN COMMON

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INTRODUCTION

- **Industry must recognize the enormity and importance of the NDI issues FDA has raised.**
- **FDA's tendency will be to restrict market access.**
- **FDA has waited over 10 years to ask for comments.**
- **Given the many issues on industry's plate, a 6-month comment period would be reasonable.**

ISSUES THAT FDA'S NDI NOTICE RAISES

- 1.** Should the term “dietary ingredient” be defined narrowly to exclude potentially thousands of ingredients?
- 2.** Should all “old” dietary ingredients that were allegedly “unapproved food additives” prior to 1994 be required to go through the NDI process?
- 3.** Should the “present in the food supply” exemption to NDI notifications only apply to foods and not food components?

ISSUES THAT FDA'S NDI NOTICE RAISES (continued)

- 4. Should safety reviews under the “reasonably expected to be safe” standard be food additive safety reviews?**
- 5. Should industry have to prove benefits in NDI notifications?**

FDA'S NARROWING OF THE DEFINITION OF "DIETARY INGREDIENT"

- DSHEA defined "dietary ingredient" very broadly to include vitamins, minerals, herbs and other botanicals, amino acids, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake," as well as concentrates, metabolites, constituents, extracts or combinations of these ingredients.
- The "dietary substance" clause was intended to capture virtually all ingredients suitable for ingestion that are not included in other categories.

FDA'S NARROWING OF THE DEFINITION OF "DIETARY INGREDIENT" (continued)

- **FDA is rejecting NDIs based on a narrow interpretation of "dietary substance" as requiring that the ingredient be "part of man's usual food or drink."**
- **This interpretation has the potential for keeping many, possibly hundreds or thousands, of dietary ingredients off the market.**

“MARKETED” OR “LAWFULLY MARKETED”?

- **The FDC Act defines the term “new dietary ingredient” in part to mean “a dietary ingredient that was not marketed in the United States before October 15, 1994.”**
- **FDA has asserted in various communications to industry that proof of “marketing” prior to 1994 is not sufficient – FDA is requiring proof of “lawful marketing,” including proof that the ingredient was not, in FDA’s view, an “unapproved food additive.”**

“MARKETED” OR “LAWFULLY MARKETED”? (continued)

- **Since virtually all dietary ingredients other than traditional vitamins or minerals on the market pre-1994 were, in FDA’s view “unapproved food additives,” this interpretation of the law would force most “old” dietary ingredients into the NDI review process or off the market.**
- **The ingredients potentially affected include evening primrose oil, black currant oil, borage seed oil, linseed/flaxseed oil, chlorella, lobelia, St. John’s Wort and most other herbs, glucosamine, chondroitin sulfate, and coenzyme Q10.**

NARROWING THE EXEMPTION FOR NDIs “PRESENT IN THE FOOD SUPPLY”

- **DSHEA exempts from the NDI notification process “dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.”**
- **In letters to industry, FDA has stated that this exemption from the notification process does not apply to ingredients such as carbohydrates, proteins, vitamins and other “inherent components” of food, but only to the whole food article itself.**

NARROWING THE EXEMPTION FOR NDIs “PRESENT IN THE FOOD SUPPLY” (continued)

- **This interpretation will force many hundreds of NDIs through the NDI review process, even though the ingredients at issue have been widely consumed in food and are obviously safe.**
- **The resultant reviews will be a needless waste of industry and FDA resources, and will result in additional NDI rejections.**

WHAT QUANTITY OF DATA IS REQUIRED TO MEET THE “REASONABLY EXPECTED TO BE SAFE” STANDARD?

- **DSHEA intended that the “reasonably expected to be safe” standard be less than the full-blown food additive safety review – however, if FDA is charged with reviewing safety, how can “less than food additive safety” be acceptable?**

WHAT QUANTITY OF DATA IS REQUIRED TO MEET THE “REASONABLY EXPECTED TO BE SAFE” STANDARD? (continued)

- **In the end, if FDA is left to its own devices, industry will end up with full safety reviews but no official FDA “approval” to use for PR.**
- **The only apparent way out of this dilemma is for industry to adopt a self-regulatory safety review, employing expert panels similar to those used in the cosmetic and flavors and extracts industries.**

SHOULD NDI REVIEWS BE “RISK/BENEFIT” REVIEWS?

- A final point of warning – FDA’s new “risk/benefit” standard for adulteration, which was adopted in the ephedra final rule, has serious implications for NDI reviews.
- NDIs are also subject to the same “unreasonable risk” standard from which FDA developed the “risk/benefit” standard.
- FDA may require that NDI notifications prove “benefits” for the ingredient at issue before FDA will file the notification.

CONCLUSIONS

- **Industry is at a crossroads with respect to FDA regulation of dietary supplements.**
- **Lax FDA enforcement of existing regulations has created a free-for-all market and bad press.**
- **Industry has begged for more regulation and stricter enforcement.**

CONCLUSIONS

(continued)

- **Industry needs to be attentive as it appears that FDA is now ready to answer the call.**
- **FDA should allow ample time for industry to consider the many important implications of the NDI notice, and to file comprehensive comments.**