Responsible Innovation in Dietary Supplements

Session 4: Promoting compliance with the NDI notification requirement

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Center for Food Safety and Applied Nutrition
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Does the FDC Act/DSHEA Provide Any Form of Market Exclusivity to Notified NDIs?

- No

Some History

- FDA has always struggled with how best to address dietary supplement safety
- Congress has pushed back against over-regulation of dietary supplements – Proxmire Amendments of 1976, Dietary Supplement Health and Education Act of 1994
- For more background -- http://www.fdalawblog.net/2011/07/fdas-ndi-guidance-and-the-18-year-cycle-of-correcting-regulatory-overreach/

NDI Notification and Exclusivity

- Pre-DSHEA GRAS Affirmations (now Notifications) and Food Additive Approvals
- Similar concept incorporated in “present in food supply” exemption in DSHEA, 21 U.S.C. §350b(a)(1)

“Present in food supply” NDIN Exemption

- No notification for an NDI is required if
- “The dietary supplement contains only 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.”
- 21 U.S.C. §350b(a)(1)(emphasis added)

What does “food” mean?

- The FDC Act states that “a dietary supplement shall be deemed to be a food within the meaning of this Act.” 21U.S.C. §321(ff)
- Therefore, the phrases “present in the food supply” and “used for food” refer to both dietary supplements and conventional foods.
- FDA’s August 2016 Draft NDI Guidance suggests otherwise.

Implications for Exclusivity

- Pursuant to the FDC Act, once an NDI that requires notification has been notified and is legally present in the food supply, any company may market the same NDI without filing a notification.

Implications (cont.)

- Market exclusivity apart from patent protection cannot be achieved without an amendment to the FDC Act.

QUESTIONS?

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