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Challenges & Opportunities in Promoting Compliance with NDI Notification

CHPA

CHPA Members who market dietary supplements

CHPA - Dietary Supplement Committee

Regulatory/Legislative topics for discussion

Product Listing

FDA Authorization of 3rd Party GMP Inspectors

NDI Notification Innovation Incentive

"Dietary Ingredient" Definition

Support Additional FDA Resources

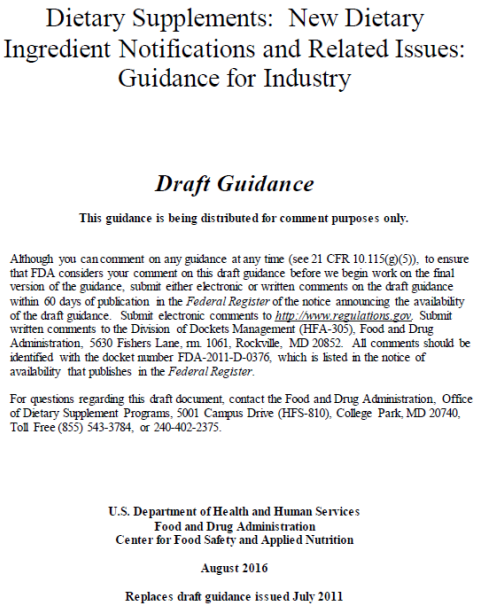
New Pathways for Health Benefit Claims

Authorized List of Old Dietary Ingredients

Options

De facto data protection via NDI Master File

- Implement NDI Master File concept as described in 2016 Guidance
- FDA position – every company marketing a NDI must file NDIN demonstrating applicable safety standard
- Subsequent filers would file own NDIN or obtain authorization to rely on innovator NDI Master File



Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2011-D-0376, which is listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Food and Drug Administration, Office of Dietary Supplement Programs, 5001 Campus Drive (HFS-810), College Park, MD 20740, Toll Free (855) 543-3784, or 240-402-2375.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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Replaces draft guidance issued July 2011

Rationale/Process

Implementation of the NDI Master File concept

- FDA must ensure safety information and other proprietary data are kept confidential beyond the 90 day premarket filing period
- FDA must take enforcement action against any entity marketing an NDI without an NDIN on file
- Similar to "Master File" process for other FDA regulated products
  - FDA lists name/owner of each Master File on website
  - Subsequent parties can obtain permission from Master File owner or perform their own safety studies

Discussion Topics – Key Points

- Would encourage additional high quality safety studies
- No diminution of the current safety standard
- FDA and industry must work together to find solutions for enforcing this provision (i.e., keeping "me too" ingredients without appropriate safety data off the market)