



NUTRITION CAPITAL NETWORK

A Discussion on the New Draft Guidance for New Dietary Ingredients Notifications

Tuesday, September 13, 2016 10am-11:00am (PST)

Agenda

Introduction

Mike Dovbish and Grant Ferrier of NCN

A Discussion on the New Draft Guidance for New Dietary Ingredients Notifications

Todd Harrison, Chair of the FDA Practice at Venable LLP

Q&A

Speakers and Audience

NUTRITION CAPITAL NETWORK'S MISSION

The mission of Nutrition Capital Network (NCN) is to:

Facilitate the financing and partnering process for small and medium-sized companies

- Introduce investors to the next generation of successful brands and technology in the nutrition, health & wellness, and natural/organic industries.
- Facilitating capital flow for the betterment of business, human health and society.

NCN accomplishes this mission by:

Creating a series of events and virtual tools to connect companies and investors

NCN's Network or 'Ecosystem'

Presenters: 508 companies have presented at 25 meetings since 2007 from a dealflow list of more than 2,400 applicants

Investors: 260 investor entities have attended NCN investor meetings from **strategic investors** in CPG, food, pharma and ingredients, to **professional investors** in private equity & venture capital and family funds, to former industry owners, high-net-worth individuals and angel investors; Cornerstone Investor members number 40+ in 2016

Sponsors: Specialist service providers: 9 in 2016 in law, IB, recruiting, PR

Selection Committee: Industry experts who help recruit, select and mentor presenting companies at each meeting: 31 in 2016

Note: NCN is a private company supported by Cornerstone Investor subscription membership fees, investor meeting registrations, sponsorship fees and presenter fees. NCN makes no fee on transactions, but principals or selection committee members may invest or take positions in NCN companies. Information provided by NCN does not constitute investment advice nor the offer to sell any securities in any jurisdiction.

NCN'S FOCUS

Companies in the nutrition and health & wellness industry across the value chain including the following:

Dietary Supplements	Ingredients & Nutrition Science
Natural and Organic Foods	Technology; Foodtech; Apps; Media
Functional Foods	Wellness Products
Healthy Foods	Natural and Organic Personal Care
Medical Foods	Natural Household Products
Sports Nutrition	Natural/Functional Pet Products

NCN 2016 FALL CALENDAR

NCN Seminar at Expo East - Baltimore

September 21, 2016; 4-5pm session; 5-6pm Pitch Slam

NCN at Supply Side West and Venture Tank: Las Vegas

October 5, 2016: 11am – 6pm; 6-7pm Venture Tank
12-15 Companies (Ingredients/Tech); 40-50 Investors

NCN XIX Fall Meeting, San Francisco

November 8-9, 2016: 1-9 pm Tuesday; 8-5 pm Weds.
20-22 Companies (All Categories); 70-80 Investors

NCN: Success Story Highlights

- **ZICO Pure Coconut Water:** NCN III in October 2008 raising \$2-3 million: NCN Cornerstone Investor member Coca-Cola invested \$15 million in 2009
- **Happy Baby:** NCN III in October 2008 raised \$500,000 in 2009: Sold to Danone in 2013 for \$100-million-plus when with sales at \$63 million.
- **Plum Organics:** NCN IV in April 2009; 2009 round led by now NCN member Alliance Consumer Growth; 2010 round \$9 million led by NCN member Catterton; Campbell acquired Plum in June 2013 with sales at \$93 million.
- **Food Should Taste Good:** NCN VI in May 2010 as portfolio company of NCN member Sherbrooke; acquired by NCN member General Mills in 2012.
- **Other brands** presented include Zevia, Annie's, Manitoba Harvest, Nawgan, Red's, Balance Water, mix1, Kevita, Suja, Runa, Angie's, Health Warrior, etc.
- **Science& Ingredients:** Biovelop-Tate & Lyle; IGY-family office, Anagenix-Stratum/Novus, Qualitas-Valicor, Lodaat, LiveLeaf, MycoTechnology, Blue Prairie, Natreon-DSM announced in July 2015

NCN INGREDIENT SUCCESSES

NCN has hosted 25 investor meetings and presented 508 companies since founding in 2007; 52% have raised capital or completed some sort of transaction.

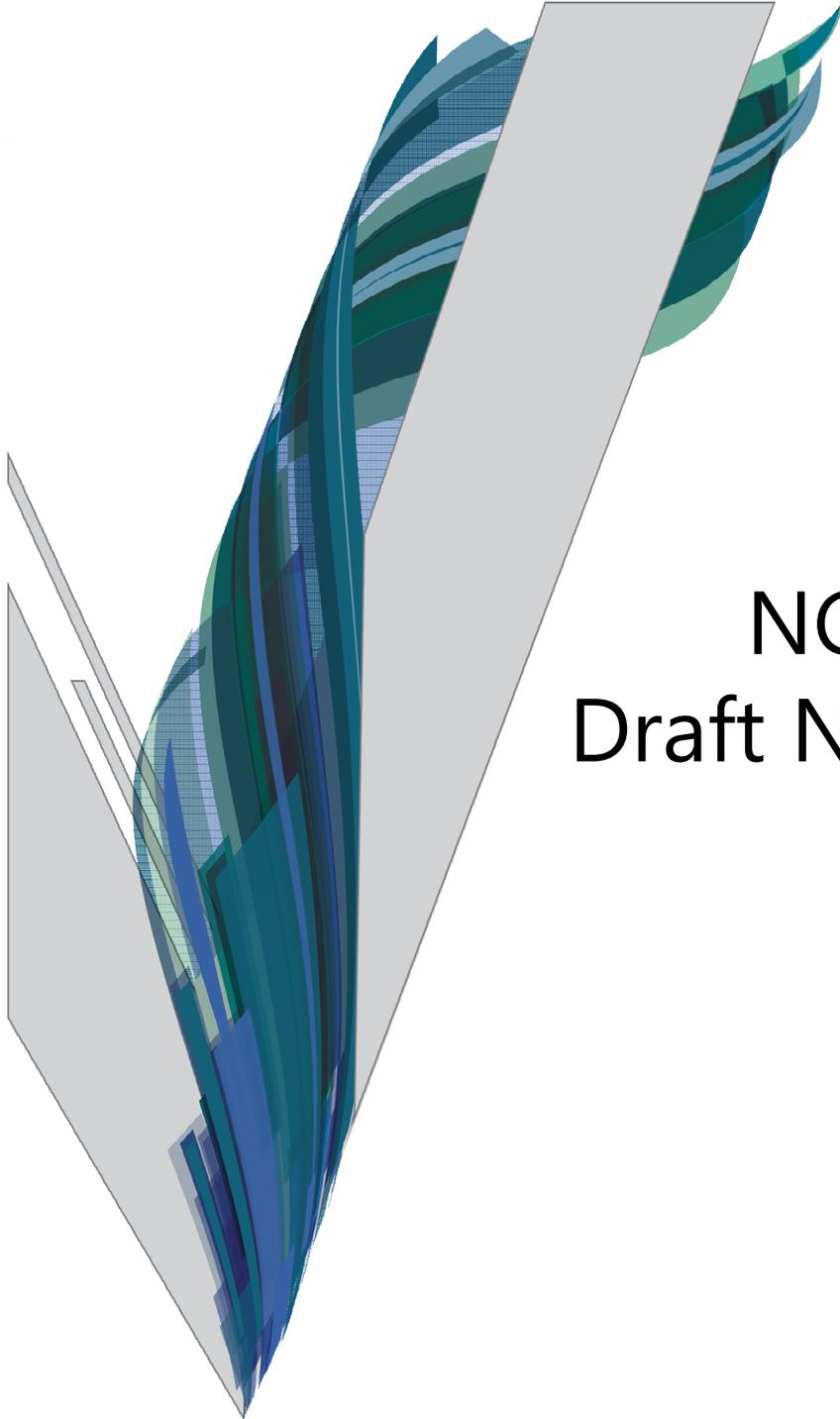
“It was through Nutrition Capital Network that we were introduced to one of our key investors and we successfully closed our \$8 million round,” said Alan Hahn, CEO and founder of MycoTechnology Inc

Natreon Inc., a supplier of science based Ayurvedic ingredients and a past NCN presenting company, recently announced an equity investment from DSM Venturing BV, the corporate venture capital arm of Royal DSM. "Our experience at NCN was very productive. We honed our business plan, met many new high-level contacts, and the recent announcement of our investment from DSM Venturing was largely the result of the NCN process," said Sanni Raju, CEO & chairman of Natreon.

NCN SPONSORS

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NCN Conference Call: Draft NDI Guidance Document

September 13, 2016
1:00 pm – 2:00 pm EST

Todd A. Harrison
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Regulatory History

The Dietary Supplement Health and Education Act of 1994 (**DSHEA**) (Pub. L. 103-417) was enacted on October 25, 1994 and amended the Food, Drug & Cosmetic Act by including regulatory requirements for dietary supplements.

“Dietary Ingredient” An ingredient of a dietary supplement must be one or any combination of the following substances:

Vitamin,

Mineral,

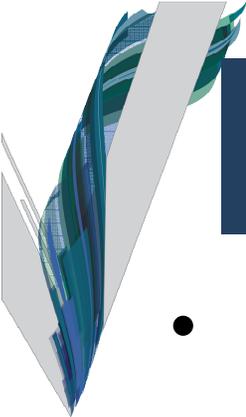
Herb or other botanical,

Amino acid,

Dietary substance for use by man to supplement the diet by increasing the total dietary intake (*e.g.*, enzymes or tissues from organs or glands), OR

A concentrate, metabolite, constituent or extract.

“New Dietary Ingredient”: A dietary ingredient that was not marketed in the U.S. before **October 15, 1994**.



Regulatory History

- Dietary ingredients marketed before Oct. 15, 1994 are “grandfathered” or “pre-DSHEA” ingredients.
- Dietary Supplements containing **New** Dietary Ingredients (“NDIs”) must submit an NDI Notification to FDA at least 75 days before marketing the product **UNLESS**:

The NDI has been present in the food supply as an article of food in a form in which the food has not been chemically altered.

- NDI Notifications must contain data demonstrating the ingredient’s safety.
- Failure to comply with NDI requirements renders the supplement **adulterated**.



Regulatory History

- NDI regulation promulgated in 1997 at 21 C.F.R. § 190.6.
- The Food Safety Modernization Act (“FSMA”) required FDA to publish a Guidance Document on NDI Notifications within 180 days of FSMA’s enactment.
- July 1, 2011: FDA published the Draft Guidance on NDI Notifications.
- August 15, 2016: FDA published a *revised* version of the NDI Draft Guidance in the *Federal Register*.

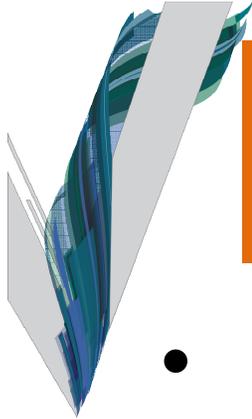




Company Responsibility and Due Diligence

- What is due diligence? Simply stated, it is taking the appropriate steps to ensure that the product being developed is safe, effective, properly manufactured, and distributed.
- The marketer of the product is ultimately responsible for: safety, efficacy, and claims.
- NDI Guidance relates to safety of products. A product is considered adulterated if the company fails to comply with NDI requirements.
- Consequences: FDA enforcement; private lawsuits.





Company Responsibility and Due Diligence

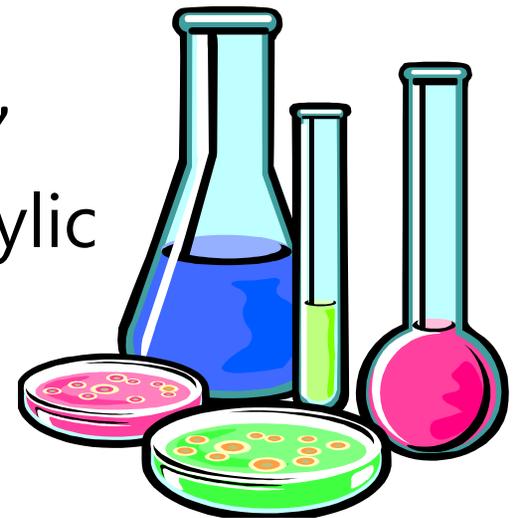
- Dos and Don'ts for NDI Due Diligence:
 - Do analytical testing.
 - Do investigate the manufacturer or ingredient supplier.
 - Are they reputable?
 - Site visit and audits
 - Don't take the supplier's word for it that you don't have an NDI issue. Do an independent analysis as (as discussed in more detail on the next slides).
 - Get an expert consultant if necessary for scientific analysis and legal counsel to review.

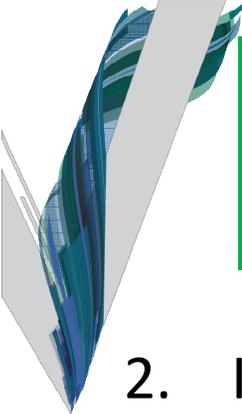




NDI Guidance Roadmap: Choose Your Own Adventure

1. Is the substance considered to be a dietary ingredient? [Y/N]
 - FDA reiterates that synthetic botanicals are **not** dietary ingredients.
 - FDA continues to define “amino acid” narrowly - “an alpha-amino carboxylic acid used as a constituent of proteins or peptides.”

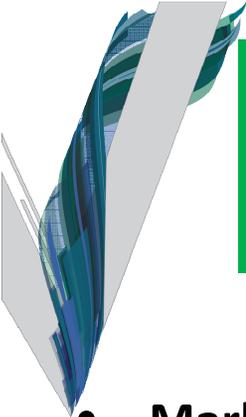




NDI Guidance Roadmap: Choose Your Own Adventure

2. Is the substance a **grandfathered ingredient** because it was marketed before Oct. 15, 1994? [Y/N] If yes, then no premarket notification is required.
- The ingredient must have been marketed prior to **Oct. 15, 1994** for use as or in a product that would *now* be considered a dietary supplement.
 - The ingredient must have been used as an ingredient and not for its technical effect on the product.



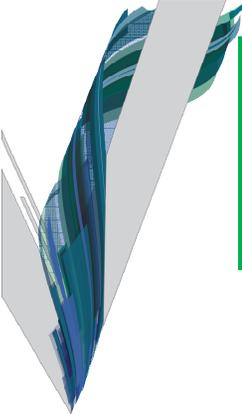


NDI Guidance Roadmap: Choose Your Own Adventure

Grandfathered Status

- **Marketing evidence:**
 - Sales records, advertisements, press releases, invoices, etc.
 - FDA will accept ingredients found in pre-DSHEA food additive and GRAS regulations to support grandfathered status. **New**
 - Affidavits and inclusion in publications such as the 1992 *Herbs of Commerce* are insufficient alone to support marketing status.
- **Authoritative List of pre-DSHEA (grandfathered) ingredients**
 - FDA will create an Authoritative List of pre-DSHEA (grandfathered) ingredients. **New**
 - Although lists developed by industry are not sufficient in FDA's view, it will depend on independently verifiable data and information submitted by industry to create its list.



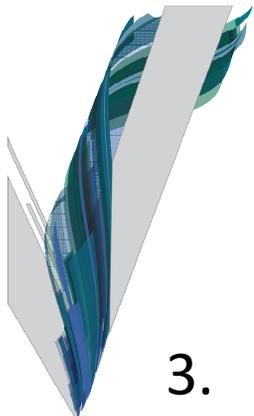


NDI Guidance Roadmap: Choose Your Own Adventure

Grandfathered Status (cont.)

- Changes in the manufacturing process may convert a grandfathered product to an NDI if the process: “alter(s) the physicochemical structure or properties, purity and impurities, **or biological properties** (such as bioavailability or toxicity) of the ingredient will result in an NDI.”
 - E.g., Using a different part of a plant would create an NDI.
 - E.g., Solution in water or tincture may change the composition of a pre-DSHEA dietary ingredient enough to make it an NDI.

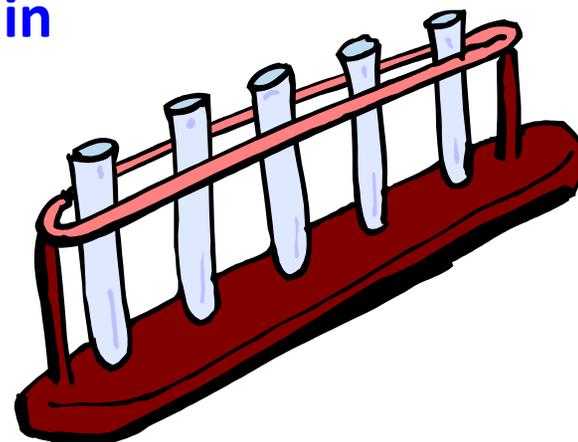


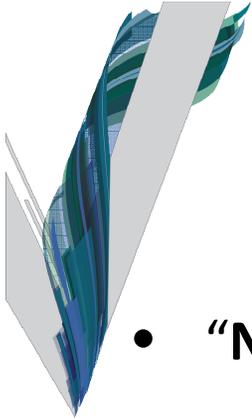


NDI Guidance Roadmap: Choose Your Own Adventure

3. If the substance is an NDI (i.e., not grandfathered), **has it been present in the food supply & not chemically altered?** [Y/N]

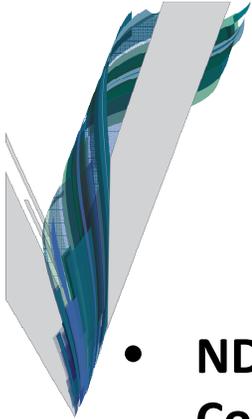
- If yes, then no premarket notification is required.
- This exemption is narrow.
- “**Present in the food supply**” means that the article must have been used in conventional food or a conventional food ingredient—not in a dietary supplement.





NDI Guidance Roadmap: Choose Your Own Adventure

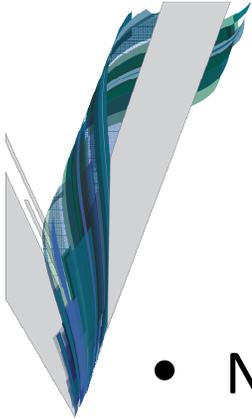
- “**Not Chemically Altered**” means a process that:
 - "involves an ingredient composed of one single raw material, or derived from a single raw material using a manufacturing process that involves only **physical steps** (e.g., water extraction and condensation); and does not involve attempts to selectively increase the concentration of particular active ingredients or cause a chemical reaction (other than esterification) that would modify the covalent bonds of any substance in the original material."
- Like the previous Draft Guidance, changing a fermentation medium from the one used to make conventional foods in the food supply is a process that would likely **chemically alter** food.
- Note: The adulteration standard of 21 U.S.C. 342(f)(1)(B) still applies, even if no NDI notification is necessary.



If the Adventure Leads to an NDI Notification...

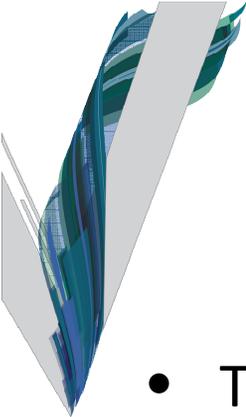
- **NDI notification must include the NDI Comprehensive Safety Profile.**
 - The Safety Profile should substantiate the safe use of the NDI in humans under the proposed conditions of use.
 - NDI Comprehensive Safety Profile that you believe to be a trade secret or confidential commercial information should be identified as such.
- **FDA will now accept NDI Master File Submissions. *New***
 - Must contain manufacturing, specifications, and other information describing the ingredient.
 - Can be incorporated by reference in NDI notifications.





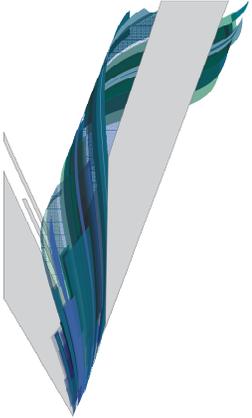
What About Multiple Products?

- No need to submit a new NDI notification for a new supplement if it contains the same NDI covered by the same company's prior submission.
- No need to submit a new NDI notification when marketing a supplement containing several pre-DSHEA ingredients that have not previously been marketed together.
- But if a company combines an **NDI** with other ingredients, a new NDI notification is required. ***New***
 - The combination triggers the new notification even if the ingredients submitted alone were received by FDA and acknowledged without objection.



Next Steps

- The new Draft Guidance is available here:
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm257563.htm>
- FDA requests comments on the New Draft Guidance by **October 11, 2016.**
- In particular, FDA is interested in comments on:
 1. Manufacturing processes that convert a grandfathered product into an NDI;
 2. Processes that “chemically alter” an ingredient present in the food supply; and
 3. How to compile independent and verifiable data to support FDA’s authoritative list.



Questions?

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