UNPA Fall 2016 Members' Meeting

UNPA team presentation

SupplySide West
Las Vegas
Oct. 6, 2016

UNPA™
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2015

WELCOME

A 50-minute snapshot.

Here we go…

UNPA © 2016

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

News of Note

- NDI Guidance
- New York AG / NBTY Settlement
- Industry M & A
- BILI – herbs and liver injury

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2016

- Canada – rethinking NHPs
  - Michael Smith, resident expert
- Homeopathy – teething pains
- China
  - The China/U.S. highway
  - A man on the ground
- MOU partner update
- Calendar and events

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2016

UNPA Educational Events at SSW 2016

- GMOs: Today's Challenges, Tomorrow's Opportunities
  - Thursday, 2-4 p.m., South Seas B
    [separate registration required]
- Counting the Cost of FDA's Draft Guidance
  - Friday, 12:30-1:00 p.m., SupplySide Central Stage
  - Loren Israelsen & Skye Lininger, co-presenters

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2016

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 20, 2016

Steven Cahillane, CEO
NBTY, Inc..
2100 Smithtown Ave
Ronkonkoma, NY 11779

Dear Mr. Cahillane:

This letter memorializes an agreement between the New York State Office of the Attorney General ("NYAG") and NBTY, Inc. ("NBTY").

Background

In early 2015, NYAG commenced an investigation into the authenticity, purity, and related marketing claims associated with certain herbal supplements sold by four major retailers in New York, including Walgreens and Walmart. NYAG commissioned a study (the "NYAG Study") that utilized DNA barcoding[1] to test specific lots of six herbal supplements, including Echinacea, Garlic, Gingko Biloba, Ginseng, Saw Palmetto, St. John's Wort, or associated extracts (the "Tested Supplements"). The Tested Supplements included specific lots of herbal supplements NBTY manufactured for Walgreens and Walmart (the "NBTY Supplements").

In letters dated February 2, 2015, NYAG informed Walmart, Walgreens, and the other retailers that the NYAG Study did not detect identifiable genetic material for the plants depicted on the relevant labels for most of the Tested Supplements, but detected DNA associated with other plants, including potential allergens, contaminants, or unlabeled fillers.

The letters expressed NYAG's concerns about the measures that manufacturers and retailers relied on to ensure the authenticity and purity of herbal supplements. As NYAG had requested, the four retailers removed the Tested Supplements from their store shelves.

[1] DNA barcoding is a technique that uses short, signature sequences of DNA to identify the plant source.

Informa Acquires Penton for $1.56 Billion

Informa expands in US market through global exhibitions and business intelligence divisions.

By Becky Peterson :: September 15, 2016

Informa will acquire Penton for $1.56 billion, in a move which will significantly increase the British company's presence in the U.S., as well as its role in the global exhibitions market.

The transaction, contingent on shareholder approval, is expected to close in Q4 and will consist of $1.46 billion in cash and $100 million in Informa stock.

Patrick Martell, CEO of business intelligence at Informa, will assume the role of CEO of Penton. Charlie McCurdy, CEO of global exhibitions, will oversee the enlarged exhibitions division.

It's not clear what role David Kieselstein, Penton CEO since 2012, will have at the company beyond the transition. But indications are that he is not staying on.

Hepatology. 2016 Sep 27. doi: 10.1002/hep.28813. [Epub ahead of print]

Liver Injury from Herbal and Dietary Supplements.

Navarro V[1], Khan I[2], Björnsson E[3], Seeff LB[4], Serrano J[5], Hoofnagle JH[5].

Author information

Abstract

Herbal and dietary supplements (HDS) are used increasingly both in the United States and worldwide and HDS induced liver injury in the U.S. has increased proportionally. Current challenges in the diagnosis and management of HDS-induced liver injury were the focus of a 2-day research symposium sponsored by the American Association for the Study of Liver Disease and the National Institutes of Health. HDS-induced liver injury now accounts for 20% of cases of hepatotoxicity in the United States based on research data. The major implicated agents include anabolic steroids, green tea extract, and multi-ingredient nutritional supplements (MINS). Anabolic steroids marketed as bodybuilding supplements typically induce a prolonged cholestatic, but ultimately self-limiting liver injury that has a distinctive serum biochemical as well as histological phenotype. Green tea extract and many other products, in contrast, tend to cause an acute-hepatitis like injury. Currently, however, the majority of cases of HDS-associated liver injury are due to MINS, and the component responsible for the toxicity is usually unknown or can only be suspected. HDS-induced liver injury presents many clinical and research challenges, in diagnosis, identification of the responsible constituents, treatment and prevention. Also important are improvements in regulatory oversight of non-prescription products to guarantee their constituents and insure purity and safety. The confident identification of injurious ingredients within HDS will require strategic alignments among clinicians, chemists, and toxicologists. The ultimate goal should be to prohibit or more closely regulate potentially injurious ingredients and thus promote public safety. This article is protected by copyright. All rights reserved.

© 2016 by the American Association for the Study of Liver Diseases.

PMID: 27677775 DOI: 10.1002/hep.28813

[PubMed - as supplied by publisher]

Publication Types

LinkOut - more resources

PubMed Commons

PubMed Commons home

Government of Canada / Gouvernement du Canada

Consulting Canadians on the Regulation of Self-Care Products in Canada

Table of Contents

1. Self-Care Products in Canada

As committed to in the Regulatory Transparency and Openness Framework, Health Canada continues to make more information available to Canadians than ever before. Canadians are also being offered more opportunities to participate in discussions on government policies and priorities. This consultation document is one such opportunity for Canadians to provide feedback at an early stage on some policy proposals under development.

Most Canadians are aware that Health Canada regulates all prescription drugs sold in Canada. You may not realize that Health Canada also regulates vitamins and minerals, probiotics, pain and allergy medications, sunscreens, make-up, skin moisturizers, and deodorants that you can purchase at a pharmacy, grocery store, or other retail location without a prescription from your doctor. Canadians use these "self-care products" frequently - sometimes on a daily basis - to care for themselves and their families, for improving appearance, maintaining health and treating minor ailments.

When shopping for a self-care product, you will often see various options grouped together on store shelves based on the condition for which they are intended to be used. For example, a wide variety of products for skin care may be grouped together or a number of different products for headache relief may sit next to each other on the shelf. Many of the products you see might make the same or similar claims about what they do and they may have packaging that all looks alike. These similarities may lead a consumer to believe that these products are equally effective and have had to follow the same rules and oversight to be allowed to be sold, but this may not be the case.

Based on definitions in legislation and regulations, Health Canada considers self-care products to be made up of three different product types:

- **Cosmetics**, which are used for cleaning, improving or altering the complexion, skin, hair or teeth, such as moisturizing creams, deodorants, and shampoos;
- **Natural health products**, which include vitamin and mineral supplements, probiotics, herbal preparations, homeopathic remedies, and traditional medicines (such as traditional Chinese medicines); and
- **Non-prescription drugs**, also commonly referred to as "over-the-counter drugs" which include products for pain relief, cold and flu symptoms, and allergy relief.

Health Canada has different ways of overseeing the safety, efficacy, and quality of cosmetics, natural health products, and non-prescription drugs. By **safety**, we mean that the product will not be harmful or toxic when you use it according to the directions and warnings on the label. **Efficacy** refers to what the product is meant to do and is usually represented by a claim, e.g., "relieves headache". A health claim is a description on the product about what it does in relation to someone's health. Finally, **quality** means that the product is manufactured under controlled conditions and will be made properly.

While all of these products fall under one law in Canada - the Food and Drugs Act - they are regulated under three separate sets of regulations:

- Cosmetics sold in Canada must meet the **Cosmetic Regulations**;
- Natural health products sold in Canada must meet the **Natural Health Products Regulations**; and
- Non-prescription drugs sold in Canada must meet the **Food and Drug Regulations.**

Regulations, along with related policy and guidance documents, set the rules that companies have to follow so that their products can be sold in Canada. These rules set out how products are evaluated and approved by Health Canada (including what claims can be made); how products should be manufactured, labelled and packaged; how safety and compliance will be monitored once products are on the market; and, what the consequences are for companies if they do not follow the rules.

UNPA © 2016

- Homeopathy
  - Is FDA corralling homeopathics?

UNPA © 2016

UNPA
UNITED NATURAL PRODUCTS ALLIANCE®

FDA News Release

FDA warns against the use of homeopathic teething tablets and gels

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

For Immediate Release September 30, 2016

Release

Español

The U.S. Food and Drug Administration is warning consumers that homeopathic teething tablets and gels may pose a risk to infants and children. The FDA recommends that consumers stop using these products and dispose of any in their possession.

Homeopathic teething tablets and gels are distributed by CVS, Hyland's, and

Inquiries

Media

Lyndsay Meyer
240-402-5345

Consumers

888-INFO-FDA

Follow FDA

Follow @US_FDA
Follow FDA
Follow @FDAmedia

Daniel Mabey – Strategic Liaison, Asia

UNPA © 2016

- Education:
  - Tsinghua University, Beijing
  - Peking University, Beijing
  - University of Pennsylvania
- Work Experience:
  - China Next Generation Education Foundation, Beijing, China -- Executive Assistant to Chairman
  - First Equity Holdings Corporation, Beijing-SLC, Senior Analyst
  - Sussex Group / Ciao Partners, Beijing-SLC, Partner

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA MOU Partnership News

- British Columbia Institute of Technology MOU agreement announced June 15
- Botanical DNA testing resource
- Canada regulatory insights
- NHP Research Society of Canada 2017 Conference, “Beyond Tradition,” May 8-12

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

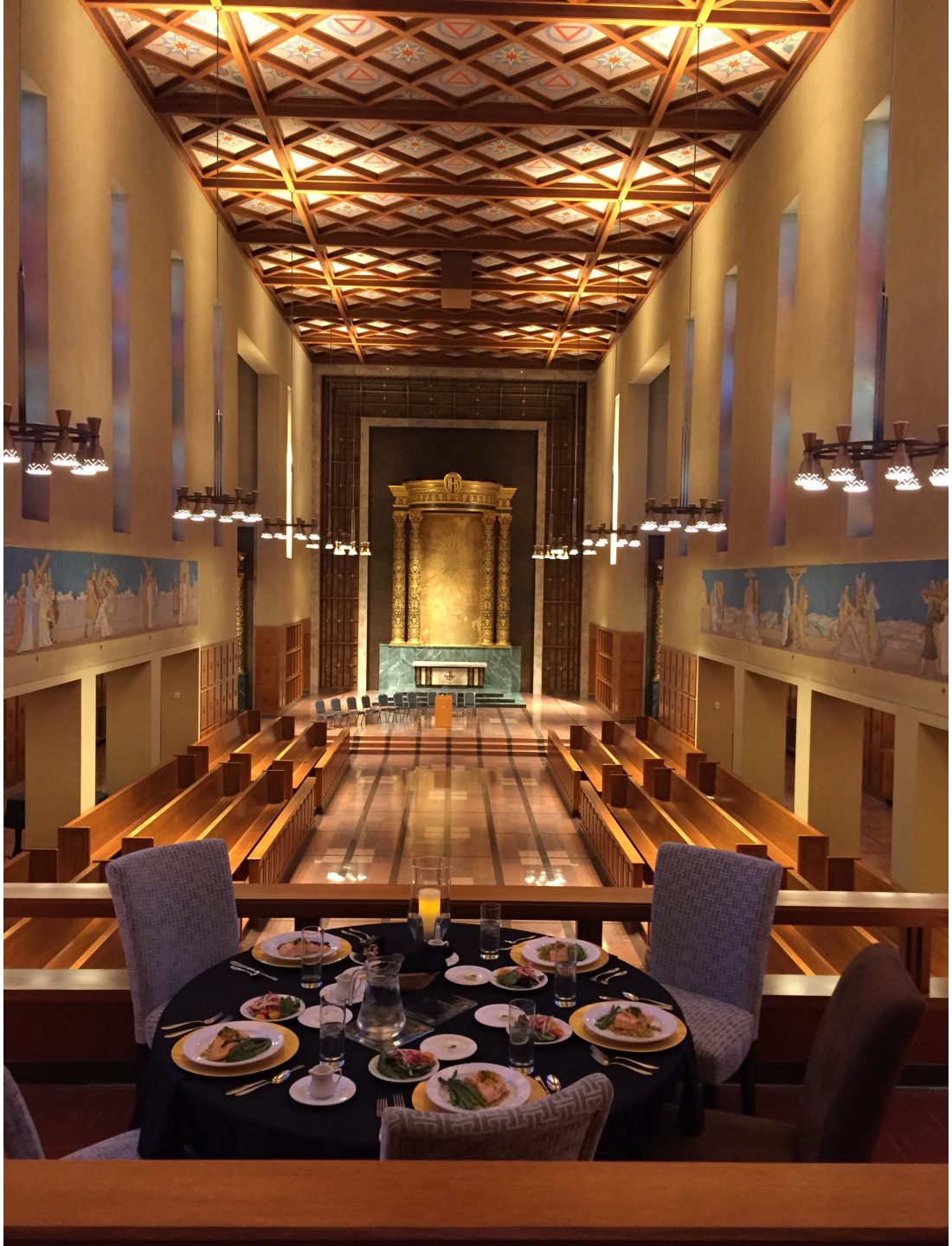
UNPA © 2016

UNPA MOU Partnership News

- Bastyr University MOU agreement announced Sept. 21
- Washington State Chapter Anchor
- Practitioner liaison to UNPA
- DS training to students

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2016



And now for the main event…

UNPA™

UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2015

The 2016 NDI Draft Guidance: A Snapshot of Key Issues

Manufacturing Changes

- Key reference – 2014 Food Additive Guidance
- All or significant changes?
- Breakout the types of changes; score relative risk and frequency of use

UNPA © 2016

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Nanotechnology

- Definition: 1-100 nanometers
- What is our position?
- What do we need to know?

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Solvents

- Only allowable pre-DSHEA solvents – water & ethanol
- Super critical CO_2
- Provide evidence of pre-DSHEA use
- Survey other solvents of interest
- Is there a need for an NDI if new solvents are used?

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Master Files

- Experts to review key issues with working group

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

ODI List

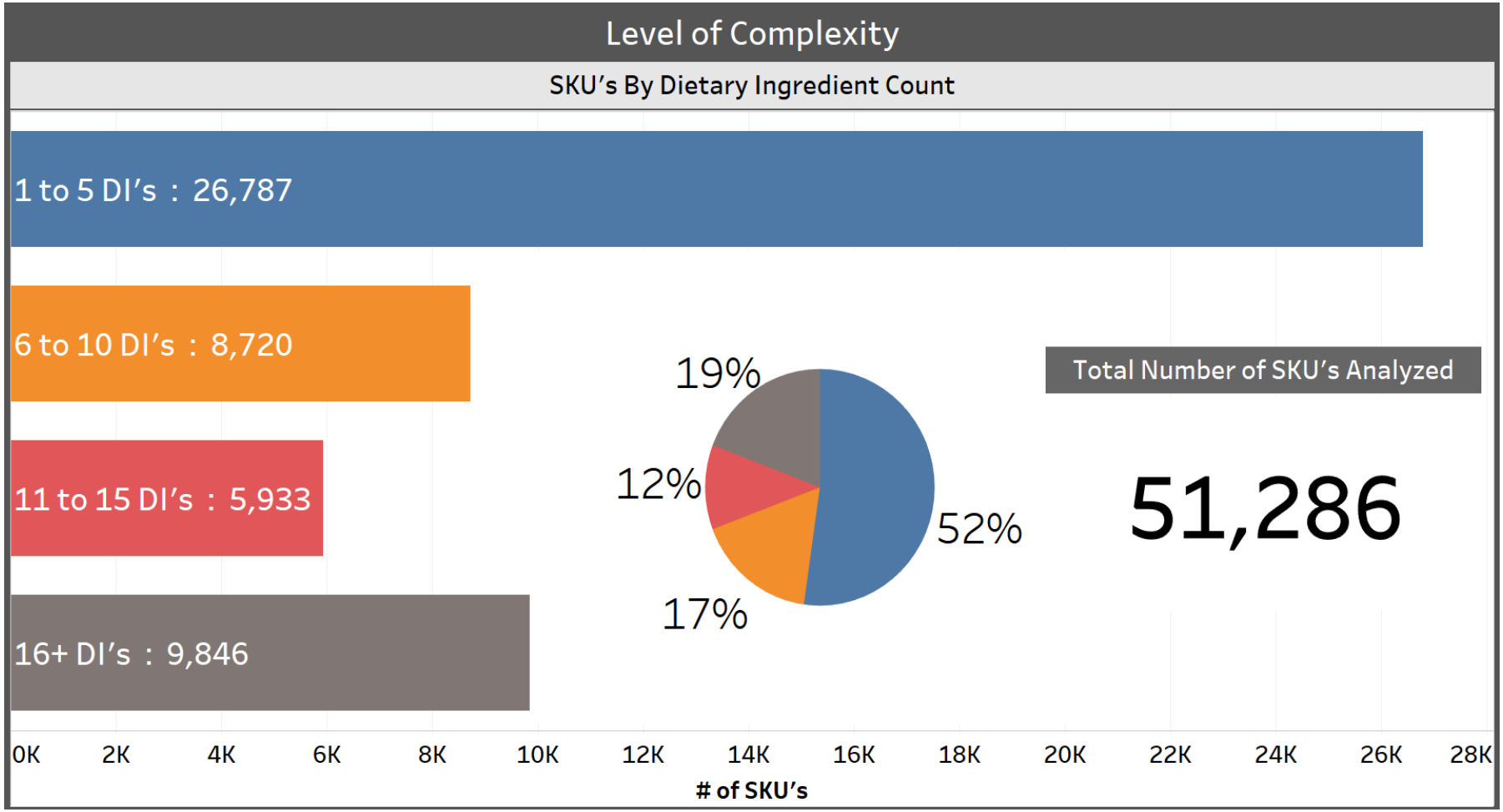
- No authoritative lists recognized by FDA
- FDA is prepared to develop an authoritative list – is this a good or bad idea?
- Save and hold pre-DSHEA records of ODI use
- UNPA to hold as an interim custodian of documents for members
- Who can we collaborate with?
- Focus on manufacturing records

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Combination policy

- The policy makes no sense – it is economically prohibitive
- Are there high risk ingredients which, if combined, should trigger NDI? If so, create inventory of high risk ingredients.

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

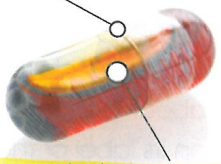

Level of Complexity
SKU's By Dietary Ingredient Count
1 to 5 DI's : 26,787
6 to 10 DI's : 8,720
11 to 15 DI's : 5,933
16+ DI's : 9,846
19%
12%
52%
17%
Total Number of SKU's Analyzed
51,286
0K
2K
4K
6K
8K
10K
12K
14K
16K
18K
20K
22K
24K
26K
28K
# of SKU's

THIS CHANGES EVERYTHING

INTRODUCING LIPOSOMAL VITAMIN C AND VITAMIN D

Featuring groundbreaking liposomal technology inside and Licaps® capsules on the outside.
The next best way your customers can take control of their health.

Licaps® capsules protect the nutrients inside, ensuring freshness and quality



Liposomal technology enhances absorption of the nutrients for optimal results

DR. MERCOLA®
PREMIUM PRODUCTS

Available In Fine Health Food Stores Nationwide

Learn more by calling 847-252-4353

Wholesale@Mercola.com

Go to www.vitaminretailer.com/mercola for info about this advertiser

DISCOVER THE MANY BENEFITS OF BERBERINE*

Berberine is a natural constituent of herbs such as goldenseal, Oregon grape, and barberry. Clinical studies have demonstrated that Berberine helps to support already normal glucose and lipid metabolism.*

Berberine is, however, known for its limited bioavailability; therefore, this product includes Caprate (C10, a Medium Chain Triglyceride) to promote optimal absorption and maintenance of gastrointestinal comfort during Berberine supplementation.*

Supports Glucose and Lipid Levels Already Within the Normal Range*

Optimal Berberine Absorption and GI Tolerability

SUPPLEMENT FACTS
Serving Size: 1 Softgel

Amount Per Serving		%DV
Calories	5	
Calories from Fat	5	
Total Fat	0.5 g	< 1%*
Saturated Fat	0.5 g	3%*
Berberine HCl (from *Berberis aristata* bark)	400 mg	†
MCT (Medium Chain Triglycerides) Oil	700 mg	†
Capric Acid (C10) (from MCT Oil)	238 mg	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Softgel Capsule (bovine gelatin, glycerin, water, caramel color), Beeswax and Sunflower Lecithin.

Not manufactured with yeast, wheat, gluten, soy, milk, egg, fish or shellfish ingredients. Produced in a GMP facility that processes other ingredients containing these allergens.

GF

PROTOCOL
FOR LIFE BALANCE®

EXPERIENCE THE PROTOCOL DIFFERENCE-LET OUR SALES SUPPORT TEAM GET YOU STARTED!

For more information or to place an order call 1-877-776-8610 or email: sales@protocolforlife.com protocolforlife.com

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Advanced Probiotic Science is in our DNA

Bluebonnet introduces high-potency, multi-strain, DNA-verified probiotics.

Once again, Bluebonnet has leveraged cutting-edge science, creating Advanced Choice® SingleDaily® Probiotics. These precision formulas are scientifically supported right down to the DNA to guarantee potency, purity and efficacy.

We start with thoroughly researched probiotic strains that are symbiotic – proven to function better together than alone. Advanced Choice® SingleDaily® Probiotics for adults provide potent digestive support via twenty symbiotic, DNA-verified probiotic strains enhanced by inulin, a natural prebiotic. Our women's formula addresses digestive and urogenital health with seven targeted probiotic strains plus cranberry.

Each strain is DNA-verified by the prestigious Pasteur Institute. State-of-the-art technology ensures that these Non-GMO† formulas – available in multiple potencies – are "made to survive" both manufacturing and the rigors of digestion. Proving that probiotics can be an exact science … if you make the Advanced Choice.

Available in multiple potencies for both men and women

Bluebonnet®
THE POWER INSIDE

Alternative Energy · Environmentally Friendly · Free of Most Allergens · Sustainable Resources · Community Outreach

25 YEARS

Available at fine natural food stores

◆ These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure or prevent any disease.

†Both dietary and other ingredients in these formulas are derived from sources that have never been genetically modified through the use of modern biotechnology.

For additional information on Bluebonnet nutritional supplements, please call **1-800-580-8866**, visit www.bluebonnetnutrition.com, or write: Bluebonnet Nutrition Corporation, 12915 Dairy Ashford, Sugar Land, TX 77478 USA.

Go to www.vitaminretailer.com/bluebonnet for info about this advertiser

#1 ABSORBED form of curcumin‡

New Supercharged Formulas!

MEMORY
Supports memory and cognitive health*

JOINT
Supports joint health and function*

CARDIO
Promotes healthy heart function*

WHOLE BODY
Supports healthy inflammatory responses for whole body benefits*

‡Scientific scrutiny revealed that Theracurmin was more bioavailable on a milligram-to-milligram basis than other leading° enhanced and regular forms of curcumin.
°As measured by SPINS 2014 data.

*These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

ORDER NOW! 1-877-551-2179 • usorderdesk@naturalfactors.com **naturalfactors.com**

Go to www.vitaminretailer.com/naturalfactors for info about this advertiser

Toxicity safety studies

- Examine the costs and necessity
- Ethical and consumer sensitivity concerns

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

History of food use

- What is our position on GRAS affirmation notification system?
- How useful is the “history of food use” pathway to DS sector?

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Chemical alteration

- This is a subset issue of history of food use and GRAS
- What chemical alterations do we think trigger loss of ODI status?

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Synthetic botanicals

- Vinpocetine example – what's next?
- Inventory present number of SynBots on the market
- Adulteration and spiking – essential oils as case study

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Economics

- Refine metrics with data experts
- Develop a costing model for working group discussion
- Create cost estimates based on various scenarios
- Request that FDA do economic impact analysis before any final guidance issues

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Congressional briefings

- Educating stakeholders and interested third parties
- Status of UNPA education and media efforts
- Senator Hatch – last standing member of Congress on this issue

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Consulting and advisory services

- Develop list of recommended consultants, law firms and advisors for NDI, GRAS and safety & tox study services

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Drug / DS race to market issue

- Vinpocetine as case study
- How many NDINs are at risk?

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

What UNPA has done

- Analyze
- Educate
- Request extension
- Brief up members and industry

…that's what we have done.

UNPA © 2016

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

Guidance Documents & Regulatory Information by Topic

Acidified and Low-Acid Canned Foods

Allergens

Biotechnology

Bottled Water & Carbonated Soft Drinks

Chemical Contaminants, Metals, Natural Toxins & Pesticides

Dietary Supplements

Eggs

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

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Contains Nonbinding Recommendations
Draft-Not for Implementation

August 2016

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

Resources

- Available in PDF (927B)
- Federal Register Notice
- Docket No. FDA-2011-D-0376 for commenting starting August 12, 2016

UNPA UNITED NATURAL PRODUCTS ALLIANCE

Conventional Medicine Wants FDA to Take Away Most Dietary Supplements

All Articles February 11, 2012

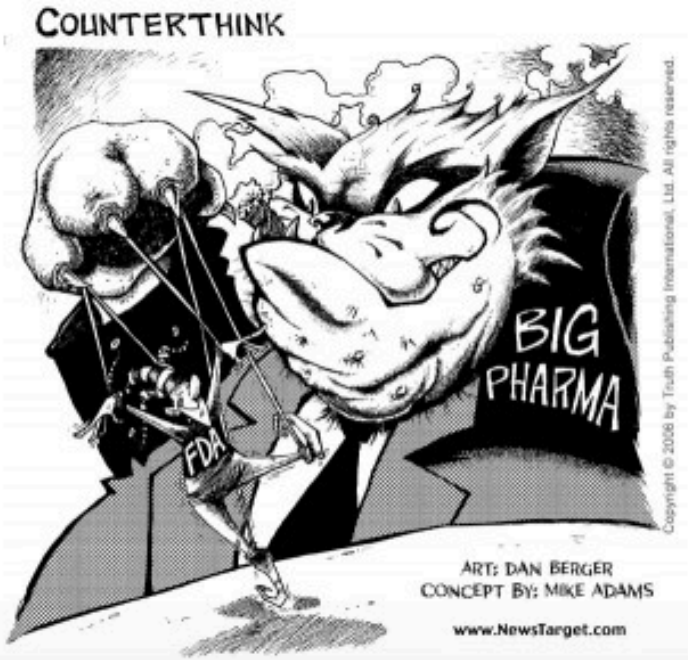
PRINT EMAIL A- A+

Tweet

G+1 Like 12 people like this.

Conventional Medicine Wants FDA to Take Away Most Dietary Supplements

An editorial in the January 25, 2012, issue of the New England Journal of Medicine strongly supports the FDA's proposed New Dietary Ingredient guidelines that would ban most of the effective nutrients you use today. One inane argument is that since some unscrupulous manufacturers are spiking their products with drugs like Viagra®, then all supplements introduced after year 1994 should be removed from the market until the FDA approves them for safety.



UNPA NDI Guidance Education

- Members conference call, Aug. 14
- 13-page Executive Summary, Aug. 14
- Economic Impact Analysis, Aug. 18
- 10-part "Did You Know" email series, starting Aug. 20
- Members webinar, Aug. 25
- "NDI Guidance II & Substances Generally Recognized as Safe Workshop," Sept. 8
- New Hope Network meeting, Sept. 13
- Rocky Mountain Dietary Supplement Forum, Sept. 14-15

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2016

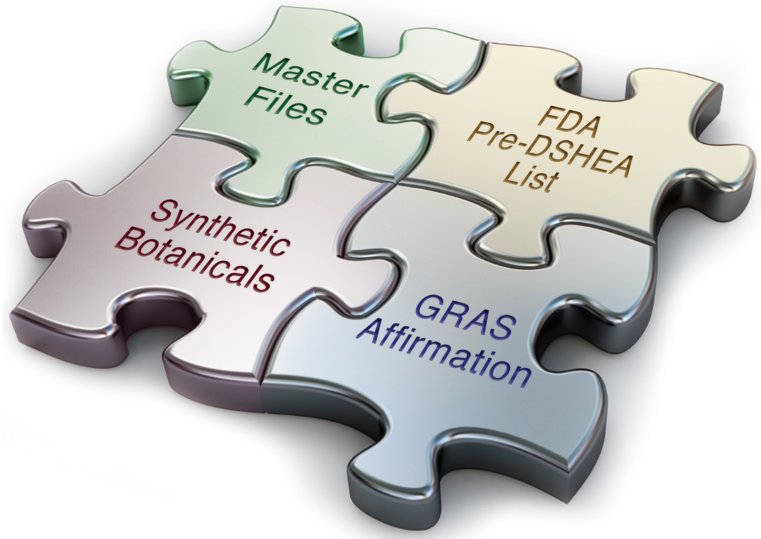
UNPAs NDI Guidance:
Did You Know? Series

Q&A about FDA's 2016 revised guidance

#1

Manufacturing Changes

In FDA's latest New Dietary Ingredients (NDIs) guidance, released on Aug. 11, 2016, a large range of "manufacturing changes" will trigger an NDI notification. Each notification requires a 75-day waiting period before you can go to market.



UNPA on the NDI draft guidance: 'The economic cost to industry could be billions of dollars'

By Stephen Daniells+

22-Aug-2016

Last updated on 22-Aug-2016 at 16:39 GMT

2 comments

How FDA's NDI Guidance Could Paralyze Industry

August 25, 2016 | Regulatory, Trends & Business

By Michael Crane

BLOG

Dietary Supplement Trade Association Projects Unprecedented Costs to Meet FDA Notification Requirement

by ,Josh Long - August 30, 2016

ADVERTISEMENT

The new Glanbia Nutritionals brings 3 businesses into 1 nutritional powerhouse.

glanbia nutritionals

Based on an initial assessment of new draft guidance published this month by FDA, a Utah-based trade organization projected the dietary supplement industry must devote billions of dollars to comply with a notification requirement rooted in a 1994 law.

FDA is charged with reviewing the safety profile of new dietary ingredients (NDIs), although the agency said it has received fewer than 1,000 safety-related dietary ingredient notifications since the 1994 Dietary Supplement Health and Education Act (DSHEA) was signed into law by President Bill Clinton.

INSIDER Law

Josh Long

UNPA

UNITED NATURAL PRODUCTS ALLIANCE

Would FDA's NDI Guidance Really Cost Industry Billions of Dollars?

September 14, 2016 | Regulatory, Trends & Business

By Michael Crane

UNITED NATURAL
PRODUCTS ALLIANCE®

BLOG

FDA Official Clarifies Agency's Position on NDI Filing Exemption

September 14, 2016

ADVERTISEMENT

Recent FDA guidance for the dietary supplement industry created some confusion over an exemption from an NDI (new dietary ingredient) filing requirement.

But an FDA official addressed the confusion last week during a United Natural Products Alliance (UNPA) workshop in Salt Lake City to discuss the 2016 draft NDI guidance.

The statements by Cara Welch, Ph.D., could help to dispel concerns that the agency is seeking to unlawfully restrict a well-known exemption from an NDI notification requirement for ingredients that have been present in the food supply and not chemically altered.

The supplement industry noticed the exemption was phrased slightly differently in the 2016 guidance than in a 2011 document.

INSIDER Law

Josh Long

Navigating the regulatory environment of dietary supplements and conventional foods can be a challenging task

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

From nanotechnology to master files, 5 things to think about from FDA's new NDI draft guidance

By Adi Menayang

19-Sep-2016
Last updated on 19-Sep-2016 at 16:17 GMT

Post a comment

More NDI training needed: A pulse on the dietary supplements industry

By Adi Menayang

20-Sep-2016

Last updated on 20-Sep-2016 at 18:06 GMT

Post a comment

BLOG

FDA Embraces Herbalife Master File Concept in NDI Guidance

by ,Josh Long - September 27, 2016

ADVERTISEMENT

Five years ago, in commenting on FDA draft guidance for the dietary supplement industry, Herbalife proposed the concept of a new dietary ingredient (NDI) master file.

Herbalife's idea was intended, in part, to reduce the burden on industry to submit to FDA duplicative NDI notifications for the same ingredient.

"A system is needed to avoid unnecessary duplication as regards NDIs for the same product sold to different manufacturers," Herbalife explained in 2011 comments filed with FDA. "Also, a number of dietary supplement manufacturers produce products containing the same ingredients. Subsequent NDI notifications for supplement compositions relying in part upon the same ingredients would refer to the relevant master files and would not

INSIDER Law

Josh Long

Navigating the regulatory environment of dietary

UNPA
UNITED NATURAL
PRODUCTS ALLIANCE

October 4, 2016

THE NATIONAL LAW REVIEW

FSMA PREVENTIVE CONTROLS

Automate Your System for Compliance - Food Safety Modernization Act

FDA Draft Guidance Tightens Requirements for New Dietary Ingredients

Wednesday, September 14, 2016

Food and Drug Administration recently released an updated version of its draft guidance on new dietary ingredients (NDIs), Dietary Supplements: New Dietary Ingredient Notifications and Related Issues. The lengthy draft guidance details FDA's thinking on determining whether an NDI notification is required, including how to determine if a substance is an NDI, exceptions to the notification requirement, NDI notification procedures and timeframes, what to include in an NDI notification, and a decision tree for NDI notification that helps companies determine whether an ingredient is an NDI and if notification is necessary.

ARTICLE BY

Hilary L. Lewis

Morgan, Lewis & Bockius LLP

Well Done: The New Source on Food Litigation and Regulation

Morgan Lewis

Biotech, Food, Drug
All Federal

RELATED

FDA Fi
Registr

Food In
POS Si

10 Key
on 510(

Advertiseme

NBJ®
NUTRITION BUSINESS JOURNAL

STRATEGIC INFORMATION FOR THE NUTRITION INDUSTRY

Volume XXI, No 7 | September 2016
newhope.com/nbj | $199

The death of innovation?

New FDA guidance on NDIs could freeze the industry in its tracks

by Todd Runestad

If you haven't read all 112 pages of the FDA's new draft guidance on NDI's, you're not alone. If you're not ready for its full rollout and enforcement, or don't have a plan to get ready, you've got plenty of company in an industry that could soon be shaken to its roots.

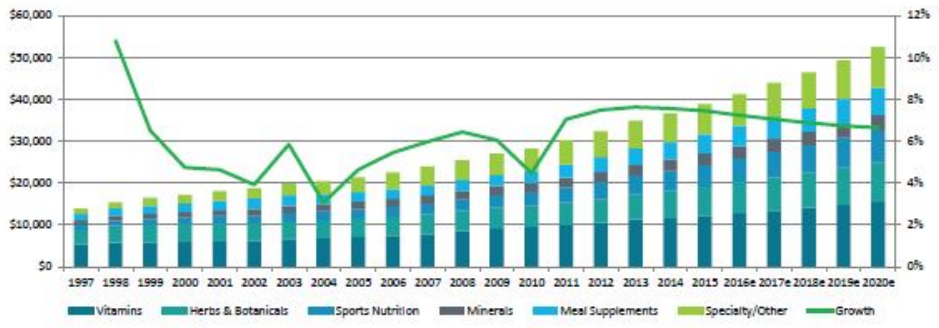
The FDA's new draft guidance on NDIs, which are new dietary ingredients introduced since the passage of 1994's Dietary Supplements Health and Education Act (DSHEA), is poised to shake up the supplements industry in more profound ways than anything since that time. It could give the FDA as much of its long sought after pre-market approval for supplements as it's going to get short of a wholesale re-write of DSHEA.

The new NDI guidance comes on top of a nearly two-year drama that's played out among attorneys general, trial lawyers and the media over the quality of supplements. The FDA says its paramount concern is

NBJ Takeaways

- New NDI draft guidance presents a wealth of unknowns
- Products already on the market could be subject to NDI
- Formulations of mutlple NDIs trigger a new NDI requirement
- Small companies could be put out of business
- NDIs could become a form of pre-market approval

SUPPLEMENT SALES AND GROWTH, 1997 TO 2020E



Source: Nutrition Business Journal ($mil., consumer sales)

CONTINUED ON PAGE 1

New Hope NETWORK

UNPA
UNITED NATURAL PRODUCTS ALLIANCE®

NDIs—is everything old new again?

A letter to the industry

By Loren Israelsen, President, United Natural Products Alliance, ww.unpa.com

On August 11, 2016, the FDA published its latest revised Draft NDI Guidance, which the agency notes is an expanded and clarified version of its 2011 Draft NDI Guidance. TheFDA also notes that the dietary supplement industry's comments and objections have been considered and taken into account.

But, in fact, we have been presented a document that envisions a dietary supplement world quite different from the one we currently live in.

How did we get here? Let's set the stage for the 22-year saga of NDIs. It is summer 1994. The Dietary Supplement Health and Education Act (DSHEA) has exploded into a heated public and congressional debate. The House and Senate negotiators (senior staff of the Hatch, Harkin, Kennedy, Dingell, Waxman and Richardson offices), together with a small group of industry leaders, are grinding out a final set of issues in hopes of reaching a compromise bill capable of passage by late October.

"Have you read the FDA's New Dietary Ingredients Guidance released Aug. 12?"

Yes: 82 %

No: 13 %

I was not aware of it: 5%

NBJ online poll

The stickiest of sticking points was the question of safety, and rightly so. What standard should apply, and would it apply to all dietary ingredients and dietary supplements, or just some?

"Do you believe the new NDI Guidance will improve public safety?"

Yes: 38% **No: 62%**

Five issues stood out:

Would the FDA have premarket approval over supplement safety?

What about "grandfathered" ingredients already on the market?

Would the safety provision apply to ingredients only or also to finished products?

What about "Old Dietary Ingredients" with a history of food use?

When does a dietary ingredient (i.e., herb, probiotic, mushroom) become so concentrated or purified that it loses its food status? What is it then?

Survey source: NBJ online poll

Underlying these issues were a set of assumptions that had been worked out and which formed the basis to answer these questions. Here are the 1994 assumptions:

Dietary ingredients and supplements are a subset of food.

Dietary ingredients and supplements are not drugs or food additives.

There is a history of safe use of dietary supplements in the United States.

Consumers want broad access to supplements at affordable prices. The only practical way to achieve this goal is to accept the prior three assumptions.

These four principles allowed the negotiating team to answer the four of those five key questions:

The FDA would not have premarket approval over supplement safety.

Supplements already on the market would be grandfathered.

The safety provision would apply to ingredients only and not finished products.

Substances with a history of food would be considered a grandfathered Old Dietary Ingredient.

Yet the August 2016 NDI guidance re-asks these 1994 questions and now comes

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

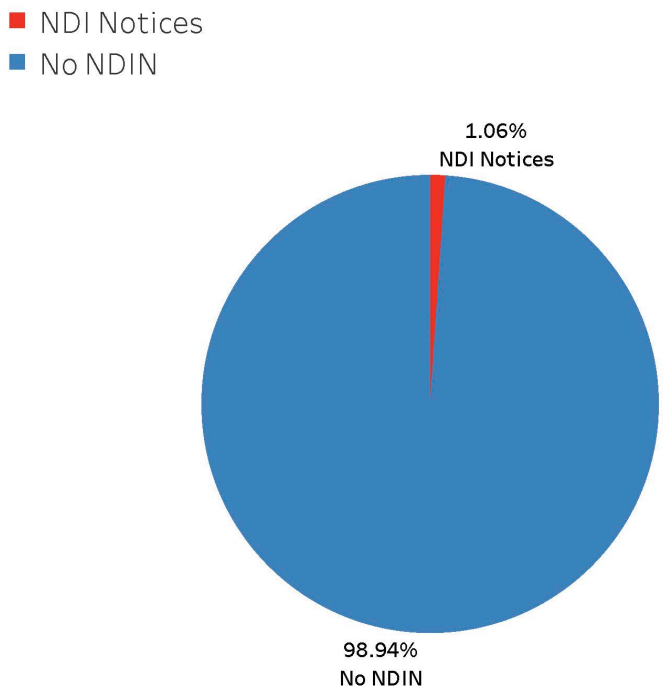
What do we do now?

- NDI working group – development of comments
- Key learnings so far:
  - World views

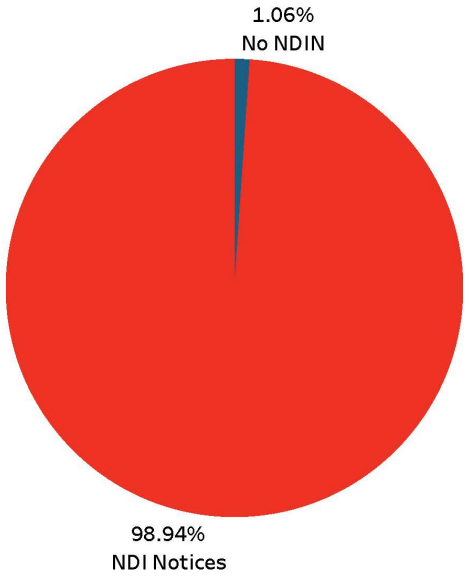
UNPA © 2016

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

DS View of the Universe - All ODI with Tiny NDI Pockets

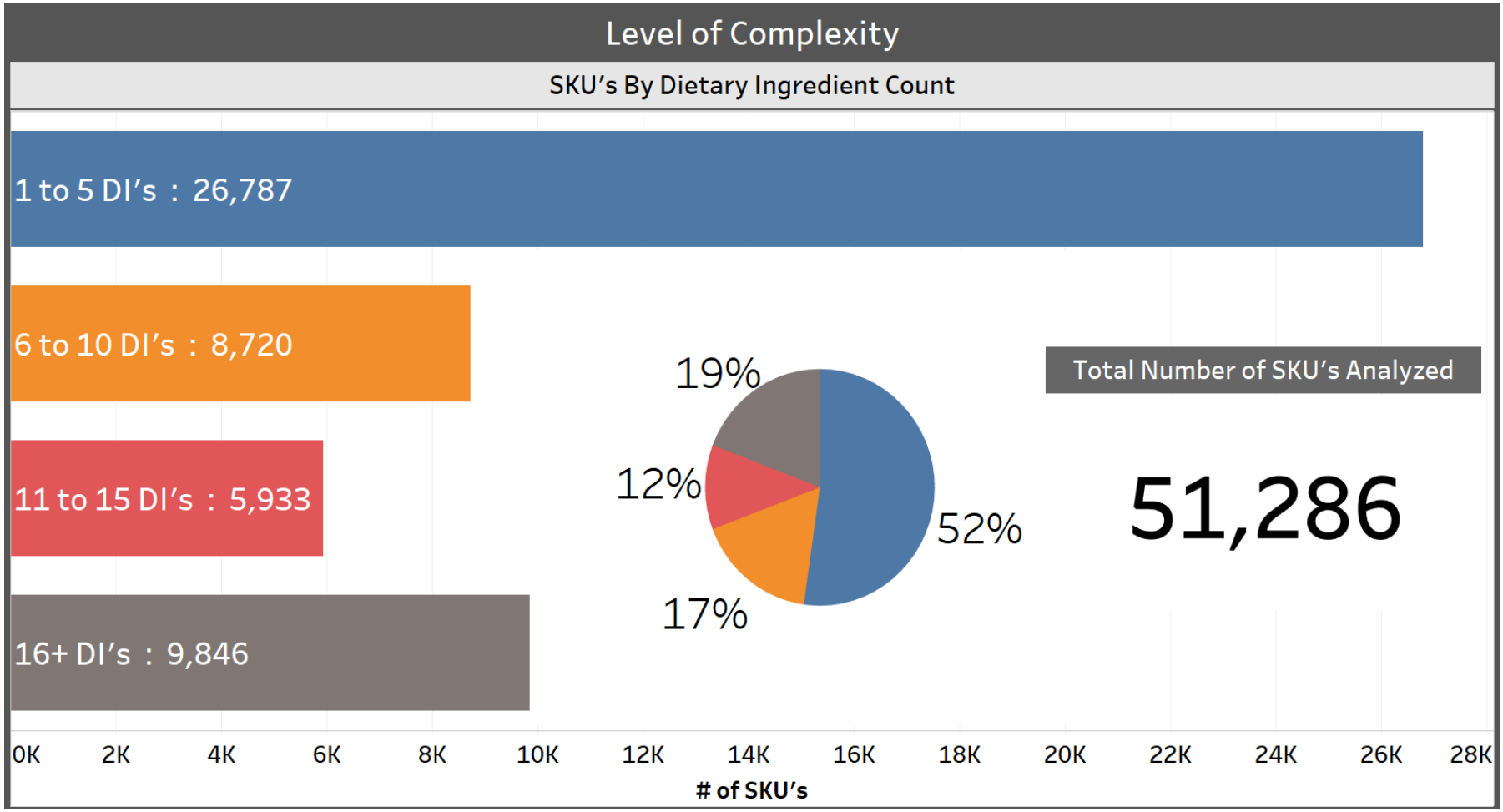


FDA View of the Universe - All NDI with Tiny ODI Pockets



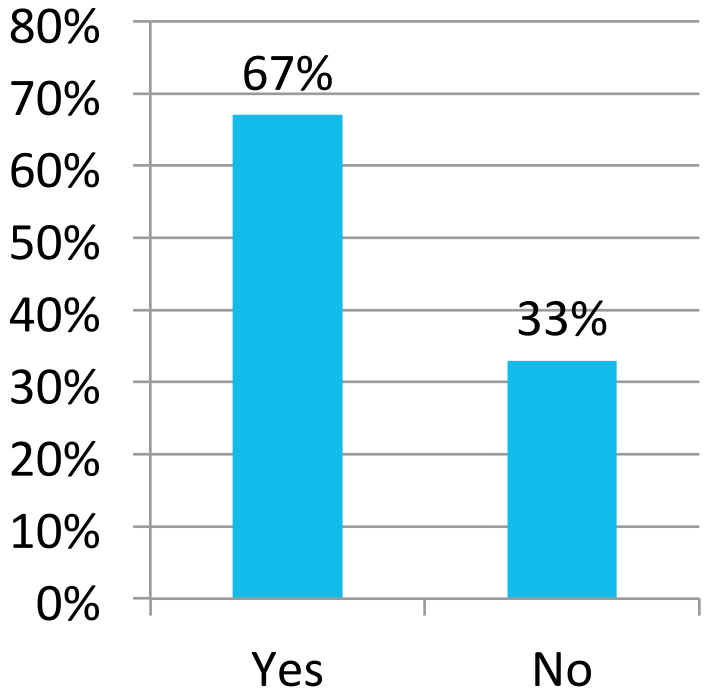
BAD ACCOUNTING

Nigeria doesn't know exactly how much oil it produces, but is pretty sure $17 billion is missing


Level of Complexity
SKU's By Dietary Ingredient Count
1 to 5 DI's : 26,787
6 to 10 DI's : 8,720
11 to 15 DI's : 5,933
16+ DI's : 9,846
19%
12%
52%
17%
Total Number of SKU's Analyzed
51,286
0K
2K
4K
6K
8K
10K
12K
14K
16K
18K
20K
22K
24K
26K
28K
# of SKU's

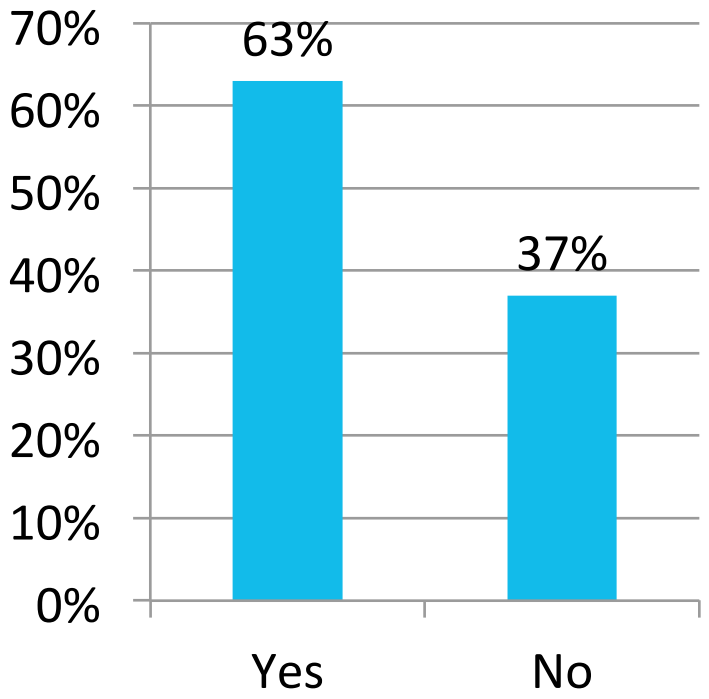
Are you concerned about doing animal studies from an ethical or reputation point of view?

1. Yes
2. No



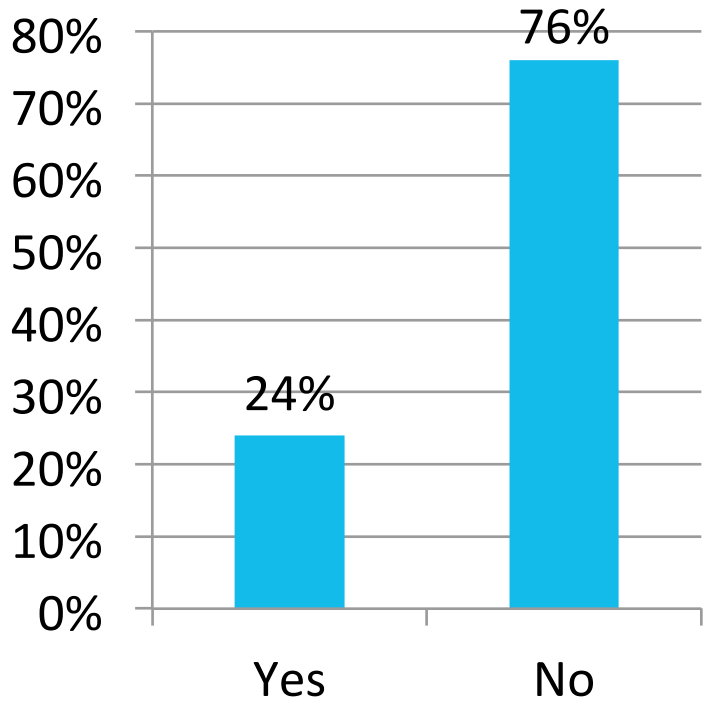
Do you produce or sell any synthetic botanicals?

1. Yes
2. No



Does your company have any experience with FDA drug master files?

1. Yes
2. No

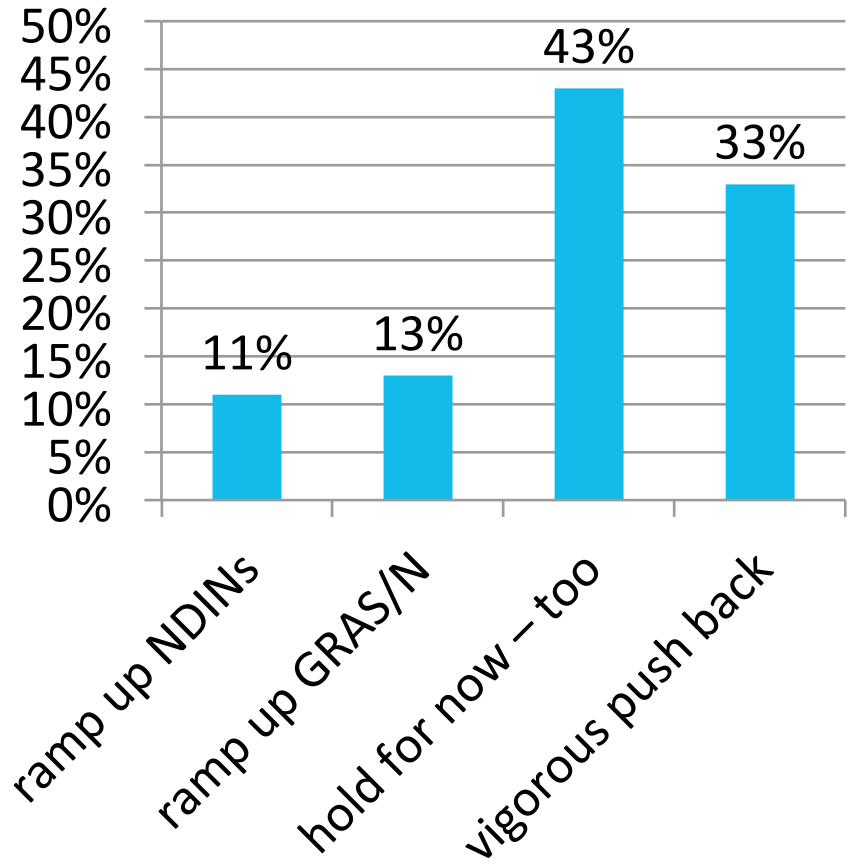


Which of the following do you currently use in the manufacture of your DI/DS?

Water extraction	84%
Ethanol	89%
Methanol	35%
Hexane	34%
Super Critical CO_2	54%
Fermentation	80%
Enzyme reactions	69%
Nano-technology	19%
Liposome technology	53%
Chelation	77%
Standardization of marker compounds	95%
Esterification	65%

For the moment, which is the better go-forward path for you?

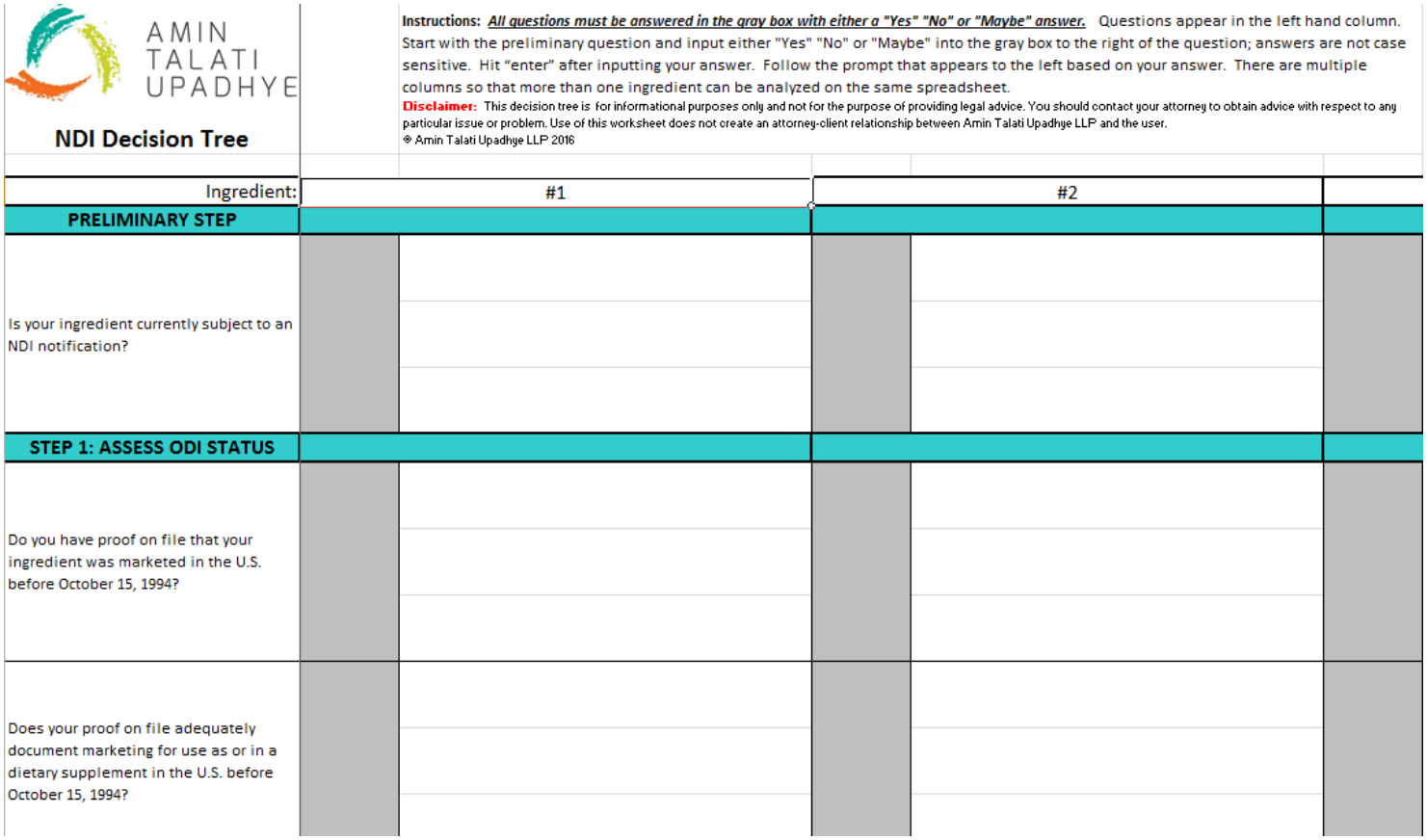
1. ramp up NDINs
2. ramp up GRAS/N
3. hold for now – too uncertain
4. vigorous push back until FDA gets it right



What do you need in the way of NDI education / training?

NDI notification tutorial?	88%
GRAS affirmation tutorial?	85%
Master files 101?	90%
Choosing the right consultants/advisors?	74%

Interactive NDI Analysis Tool Developed by Amin Talati & Upadhye



AMIN TALATI UPADHYE

NDI Decision Tree

Instructions: ***All questions must be answered in the gray box with either a "Yes" "No" or "Maybe" answer.*** Questions appear in the left hand column. Start with the preliminary question and input either "Yes" "No" or "Maybe" into the gray box to the right of the question; answers are not case sensitive. Hit "enter" after inputting your answer. Follow the prompt that appears to the left based on your answer. There are multiple columns so that more than one ingredient can be analyzed on the same spreadsheet.

Disclaimer: This decision tree is for informational purposes only and not for the purpose of providing legal advice. You should contact your attorney to obtain advice with respect to any particular issue or problem. Use of this worksheet does not create an attorney-client relationship between Amin Talati Upadhye LLP and the user.

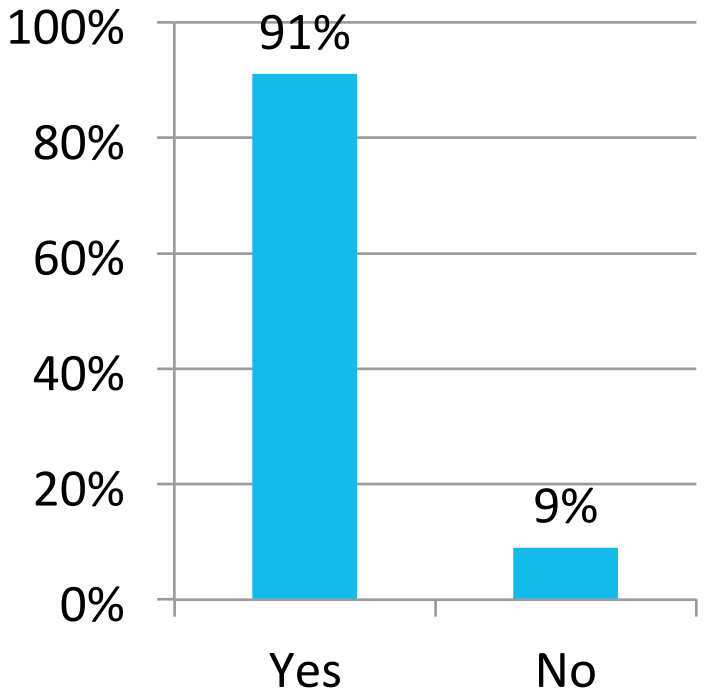
® Amin Talati Upadhye LLP 2016

Ingredient:	#1	#2	
PRELIMINARY STEP			
Is your ingredient currently subject to an NDI notification?			
STEP 1: ASSESS ODI STATUS			
Do you have proof on file that your ingredient was marketed in the U.S. before October 15, 1994?			
Does your proof on file adequately document marketing for use as or in a dietary supplement in the U.S. before October 15, 1994?			

Email: ashish@amintalati.com for a copy

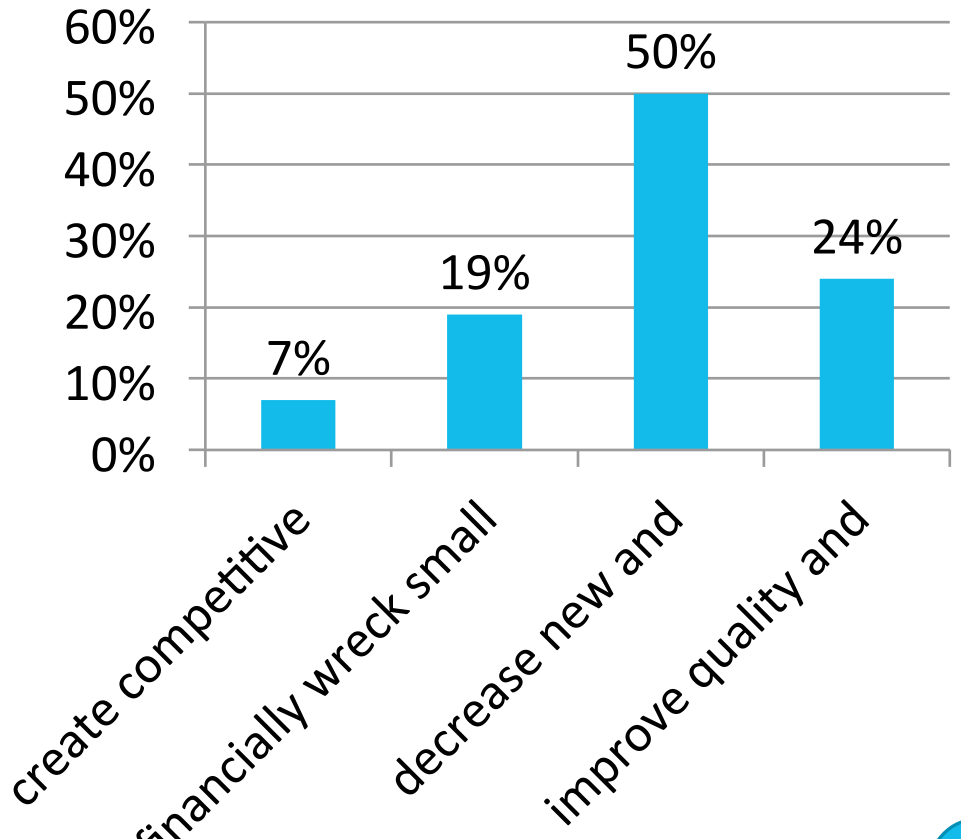
ODI list shared resource initiative?

1. Yes
2. No



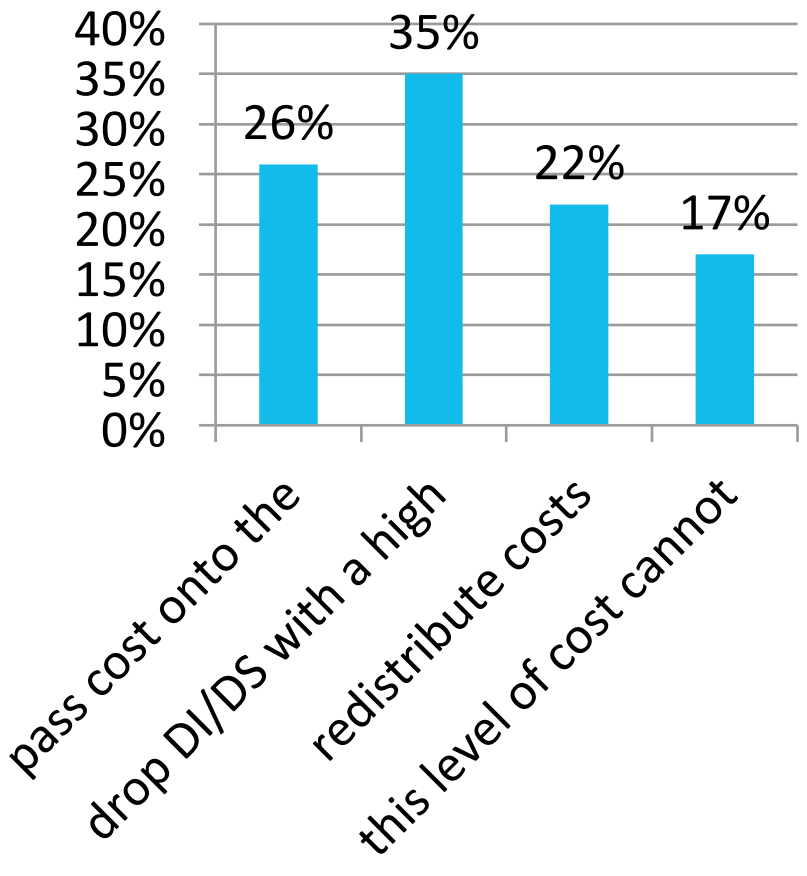
Will the 8-12-16 NDIG:

1. Create competitive opportunity
2. Financially wreck small companies
3. Decrease new and innovative products
4. Improve quality and safety



How will industry absorb new NDI/GRAS costs?

1. Pass cost onto the customer
2. Drop DI/DS with a high NDI exposure
3. Redistribute costs within the supply chain
4. This level of cost cannot be absorbed

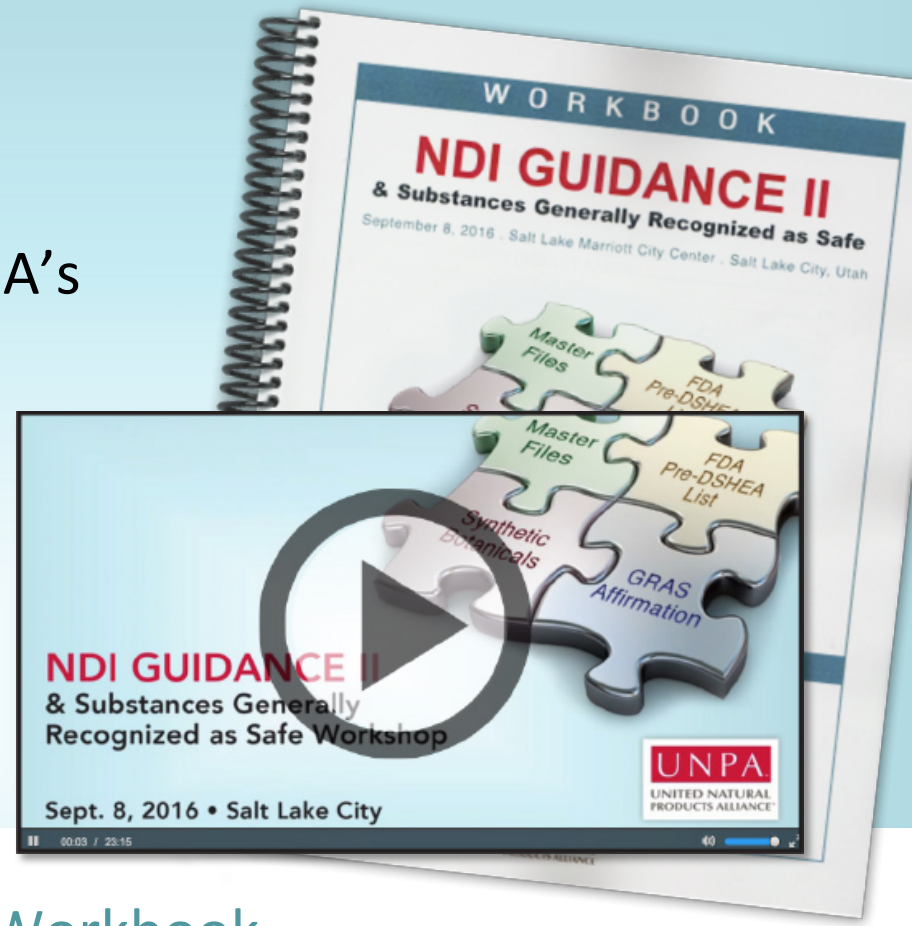


Now Available!

The complete proceedings from UNPA's

NDI GUIDANCE II

& Substances Generally Recognized as Safe Workshop



Audio, PowerPoint and Complete Workbook

$595 // $295 for UNPA members (Use code NDI)

Prices include 160-page hard copy workbook

For more information and to order, visit: www.unpa.com/store

And now…
for the good news…

UNPA™

UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2015

2016 NSF/UNPA Trainings

- **CFR 111 Dietary Supplement GMP Overview** • Oct. 25-26, *Costa Mesa, Calif.*
- **Corrective Action Management** • Oct. 27, *Costa Mesa, Calif.*
- **SOP and Record Keeping** • Oct. 28, *Costa Mesa, Calif.*
- **CFR 111 Dietary Supplement GMP Overview** • Nov. 15-16, *Tukwila, Wash.*
- **Vendor Qualification & Audit Training** • Nov. 17, *Tukwila, Wash.*
- **Corrective Action Management** • Nov. 18, *Tukwila, Wash.*
- **CFR 111 Dietary Supplement GMP Overview** • Nov. 29-30, *Phoenix*
- **Top 10 Ways to Get a Warning Letter** • Dec. 1, *Phoenix*
- **CFR 111 Dietary Supplement GMP Overview** • Dec. 7-8, *Ft. Lauderdale, Fla.*
- **Top 10 Ways to Get a Warning Letter** • Dec. 9, *Ft. Lauderdale, Fla.*

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2016

UNPA 2017 Calendar

- NDI Guidance III, Salt Lake City, Feb. 9-10*
- Expo West Members' Meeting, March 9
- ICSB, Oxford, Miss., April 3-6
- Members' Retreat, Santa Fe, N.M., May 23-25
- UNPA/IADSA Global Regulatory Update, Salt Lake City, June 22-23*
- SSW Members' Meeting, Las Vegas, Sept. 28
- Science, Testing & Technology Summit, Salt Lake City, Oct. 19-20*

**Tentative*

UNPA
UNITED NATURAL PRODUCTS ALLIANCE

UNPA © 2016

The 2017 UNPA Members' Retreat

May 23-25, 2017

LaFonda on the Plaza
Santa Fe, New Mexico

Dr. Low Dog
Keynote Presenter

Sen. Tom Harkin
Invited

Sen. Martin Heinrich
Invited

Utah Attorney General Sean Reyes

UNPA™

UNITED NATURAL PRODUCTS ALLIANCE®

Thank You

United Natural Products Alliance
1075 E Hollywood Ave
Salt Lake City, UT 84105
801.474.2572
info@unpa.com
unpa.com

UNPA © 2016