25 Years of DSHEA: A Historical Perspective

Loren Israelsen
President, United Natural Products Alliance

19th Annual Oxford ICSB
Oxford, Mississippi
April 8, 2019

UNPA
UNITED NATURAL PRODUCTS ALLIANCE®

And…

Why life sucked before DSHEA.

The Shaker Family at Sabbathday Lake

Seated: Brother Theodore Johnson, Sister Elizabeth Dunn, Sister Elsie McCord, Sister Mildred Barker, Sister Minnie Green. Standing: Brother Stephen Foster, Brother David Bertie, Sister Marie Burgess, Sister Frances Carr.

EARLY SHAKER SPIRITUALS

:A

rolling deep
ger and thirst

Of writing about the American Shakers there is no end. This two-hundred-year-old millenarian, celibate, communistic sect has gained attention greatly disproportionate to its size. Articles and books, pamphlets and parts of books discuss its theology and its influence upon other communitarian ventures, its barns and its cookery, its dances and its drawings, but particularly its crafts: chairs and candlestands, cabinets and clocks, tinware and

SIDE B

I never did believe
O holy Father

Varro E. Tyler, Ph.D.

Norman R. Farnsworth, Ph.D.

The Advent of Synthetic Chemistry

- Wonder drug
- Wonder business
- Comparative ease of regulation

SUBJECT: Botanical Products for Use as Food

BACKGROUND

CFSAN receives numerous inquiries from the public concerning the food additive status of various botanical products, most of which have some history of medicinal use but have little or no history of use as food. Many of these botanical products are referred to CFSAN by the Center for Drugs and Biologics after the therapeutic claims have been removed from the labeling of these products. Other products are presented to the agency without labeling, e.g., bulk shipments, but are assumed by the agency to be, or are represented to the agency as, products that are intended for use as food. There is also a category of botanical products that includes ethnic foods that are represented to the agency as being consumed in other countries but that are unknown for any use in the United States of America.

FDA has stated that a prior history of use of the product or ingredient as a drug would not provide support for establishing a history of use in food. The agency has also stated that the removal of therapeutic claims from product labels does not automatically convert these products to foods, especially in the the absence of a history of food use for the products. FDA has expressed its belief that the purpose of such relabeling is to circumvent the drug provisions of the Federal Food, Drug, and Cosmetic Act. When such relabeling occurs, however, the agency has found that it may be unable to prevent the marketing of these products in the absence of any scientific support that the products are toxic in the quantities offered for consumption.

In the past, FDA has detained and barred many herbs from entry into this country on the basis that they had no history of common use as food in the USA, and therefore did not qualify for GRAS status based on their history of use. On September 15, 1983, the United States Court of Appeals for the Ninth Circuit declared regulation 21 CFR 170.3(f), which restricted "common use in food" to use in the USA, to be invalid. Fmali Herb, Inc. v. Heckler, 715 F. 2d (9th Cir. 1983). As a result of this ruling, the agency can no longer impose such a restriction. The court ruling, combined with allegations of previous foreign food use and a manufacturer's ability to market foods based on independent GRAS determinations, make it necessary for CFSAN to be prepared to demonstrate that a substance is not GRAS and thus is an unsafe food additive based upon scientific evaluation. The agency published a proposal (50 FR 27294) that identifies factors that FDA will consider in determining whether a substance with a long history of use in a foreign country qualifies the substance for GRAS status

Nutrition Facts: Good Idea

Nutrition Facts

Serving Size 1 Piece (35g)
Servings Per Container 12

Amount Per Serving	
Calories 570	Calories from Fat 560
	% Daily Value*
Total Fat 63g	**97%**
Saturated Fat 7g	**35%**
Trans Fat 0g	
Cholesterol 10mg	**3%**
Sodium 140mg	**6%**
Total Carbohydrates 3g	**1%**
Dietary Fiber less than 1g	**3%**
Sugars 0g	
Protein 1g	

Vitamin A 4%	• Vitamin C 20%
Calcium 2%	• Iron 4%
Vitamin D 2%	

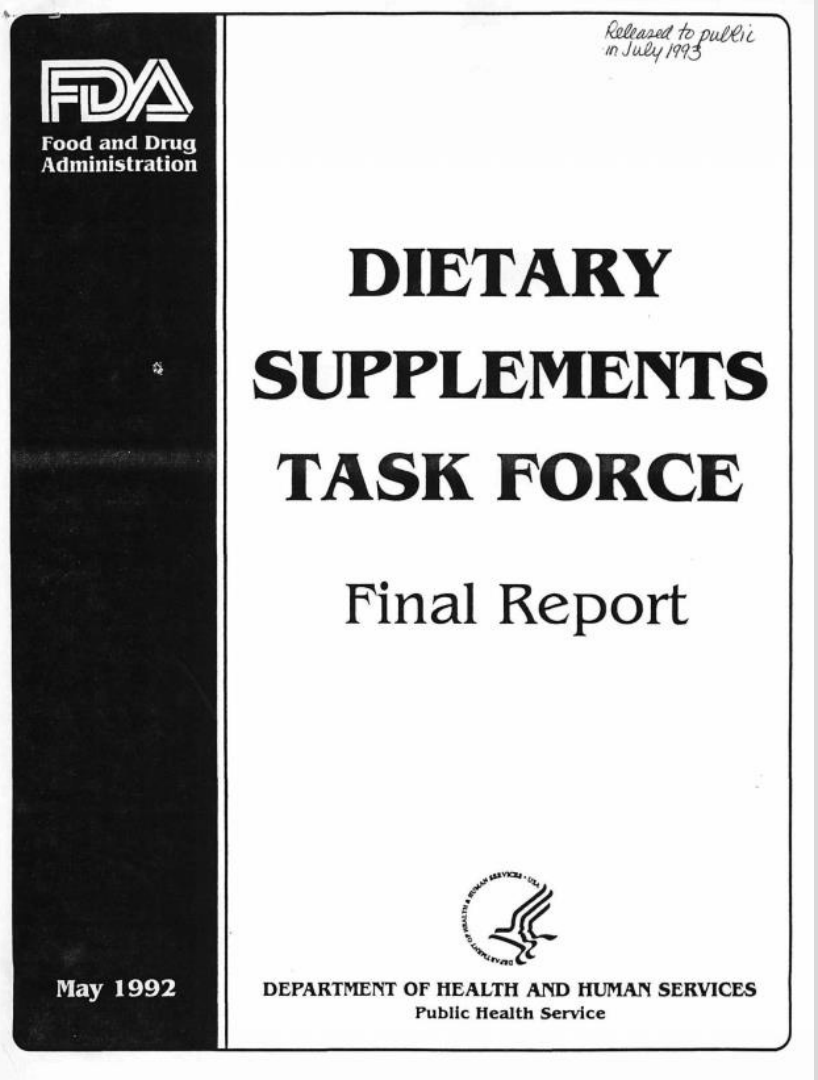
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohyrdates 4 • Protein 4

Health Claims: Good Idea

Things get suckier…


Released to public
in July 1993
FDA
Food and Drug
Administration
DIETARY
SUPPLEMENTS
TASK FORCE
Final Report
May 1992
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

- This report (also known as the Dykstra Report) was requested by Commissioner David Kessler and offered general findings and conclusions that:
  - The regulatory framework for supplements was inadequate.
  - Many dietary supplements are of uncertain safety.
  - Botanicals and amino acids in particular present the greatest safety concerns.
  - Many botanicals and amino acids can and should be regarded as drugs or unapproved food additives.

EUROPEAN-AMERICAN PHYTOMEDICINES COALITION

CITIZEN PETITION TO AMEND FDA's OTC DRUG REVIEW POLICY REGARDING FOREIGN INGREDIENTS

Robert G. Pinco, Esq.
Loren D. Israelsen, Esq.
Counsel for EAPC

July 24, 1992

MEMBERS OF EAPC

Bioforce (Netherlands)

Bioforce AG (Switzerland)

Bioforce of America (U.S.A.)

Boehringer-Ingelheim (Germany)

Indena (Inverni Della Beffa S.p.A.) (Italy)

Institut Henri Beaufour (France)

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Lichtwer US (U.S.A.)

Madaus AG (Germany)

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Pharmaton S. A. (Switzerland)

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Dr. William Schwabe GmbH & Co (Germany)

Botanicare Natural Products (Israel)

EUROPEAN-AMERICAN

PHYTOMEDICINES COALITION

CITIZEN PETITION

TO AMEND

FDA'S

MONOGRAPH ON NIGHTTIME SLEEP-AID DRUG PRODUCTS

FOR OVER-THE-COUNTER ("OTC") HUMAN USE

TO INCLUDE VALERIAN

Robert G. Pinco, Esq.
Loren D. Israelsen, Esq.
Counsel for EAPC

June 7, 1994

102D CONGRESS
2D SESSION

S. 2835

To amend the Federal Food, Drug, and Cosmetic Act to establish provisions regarding the composition and labeling of dietary supplements.

IN THE SENATE OF THE UNITED STATES

JUNE 11 (legislative day, MARCH 26), 1992

Mr. HATCH introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish provisions regarding the composition and labeling of dietary supplements.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Health Freedom Act of 1992".

SEC. 2. DEFINITIONS.

(a) DIETARY SUPPLEMENT.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following new paragraph:

One Hundred Third Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday,
the twenty-fifth day of January, one thousand nine hundred and ninety-four

An Act

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Dietary Supplement Health and Education Act of 1994".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

Somehow we are back to botanical medicines.

Drug Information Association

"Phytomedicines Development:Botanicals for the Twenty First Century"

February 24-26, 1998
The Mount Nelson Hotel
Cape Town, South Africa

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Floyd Leaders, PhD
Botanical Enterprises, Inc.
Rockville, MD 20850

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- Summarized Pharmacological Effects
- Documented Indications & Summary of Other Usage
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- Modes of Administration & Typical Dosage
- Literature Citations
- Safety & Toxicity Issues
- Characterization & Standardization of Botanicals
- Regulatory & Control Initiatives

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Friday, May 21, 1999 - Los Angeles, CA
Friday, June 4, 1999 - Dallas, TX
Friday, June 11, 1999 - Chicago, IL

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Tieraona Low Dog, MD, AHG, *Department of Family Practice,* University of New Mexico Health Sciences Center

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Bioresources International, Inc.
Botanica Labs International, Inc.
East Earth Herb Inc.
Forest Stewardship Council
The Healing Forest Conservancy
Parcelsian, Inc.
Pharmacognetics, Inc.
Phytera, Inc.
Shaman Pharmaceuticals, Inc.
Trinity Alps Botanicals
Univera Phytoceuticals, Inc.
USDA Forest Service
Wakunaga of America Co., Ltd.
Xechem, Inc.

Benefit from 12 results-oriented case studies and strategies from savvy firms that are utilizing and profiting from the biodiversity of medicinal plants!

- Phytera's Concept-to-Reality Case Study of the Pharmaceutical Potential of Plant Cell Culture
- Univera Phytoceuticals' Documentation, Handling and Processing Standards
- Andes Pharmaceuticals' Bioprospecting Paradigm Shift from "Extractive" to "Partnership" Model
- East Earth Herb's Protocols for Preparing an IND for an Herbal Product
- Shaman Pharmaceuticals' Ethnobotany Approach to New Drug Discovery
- Bioresources International's Case Study of Commercializing MIRACULIN

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Power-Packed Panel Discussion: Forging a Closer Relationship among the Botanical, Phytopharmaceutical and Ethical Pharmaceutical Industries

National Institutes of Health
National Institute of Environmental Health Sciences

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Raleigh, NC

FIM (The Foundation for Innovation in Medicine)
10th Nutraceutical Conference

NUTRACEUTICALS & PHARMACEUTICALS TAKEN TOGETHER: A NEW HEALTH SECTOR

-plus-

A New FIM Congressional Proposal: The Nutraceutical Research & Education Act - NREA

November 10/11, 1998 *The Waldorf-Astoria, New York*

Nutraceuticals (include the legal-regulatory entities dietary supplements, foods and medical foods) are being consumed together with pharmaceuticals by a large percentage of the U.S. population. We must assume that, to a significant degree, nutraceuticals and pharmaceuticals interact with each other, having a significant impact on disease - either beneficially or detrimentally. There is little doubt that this potentially enormous new health sector already exists. There is also little doubt that the medical community, health industry, and federal government are not addressing this new explosive health sector.

FIM announces a 1½ day conference which will present the current information on the business and regulatory aspects of foods, medical foods and dietary supplements. Also included will be presentations on actual or virtual clinical trials of nutraceuticals and pharmaceuticals taken together. A medicine versus law panel regarding claims will follow each presentation. The physicians will propose claims based on the clinical data itself. The lawyers will propose claims based on federal law and regulations.

Products to be discussed are Benecol, Ocean Spray Cranberry Juice, St. John's Wort, Intelligent Quisine, Zocor, Cispro, Prozac and Antihypertensive Pharmaceuticals.

The Nutraceutical Research & Education Act - NREA

In 1991 FIM published its white paper, "The Nutraceutical Initiative: A Proposal for Economic and Regulatory Reform". In it, FIM called for Congress to enact The Nutraceutical Research & Education Act - NREA. We believe that this proposal may be a timely solution to the current state of confusion which would expedite the establishment of a vigorous research-oriented nutraceutical industry.

Authorities from various health sectors will participate and make comments and recommendations on the FIM proposal, including members of Congress, both the House and the Senate, corporate, medical and legal thought leaders, who play key roles in formulating U.S. health policy. There is little doubt that the time has come for new nutraceutical laws and regulations.

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Hotel del Coronado, San Diego, CA

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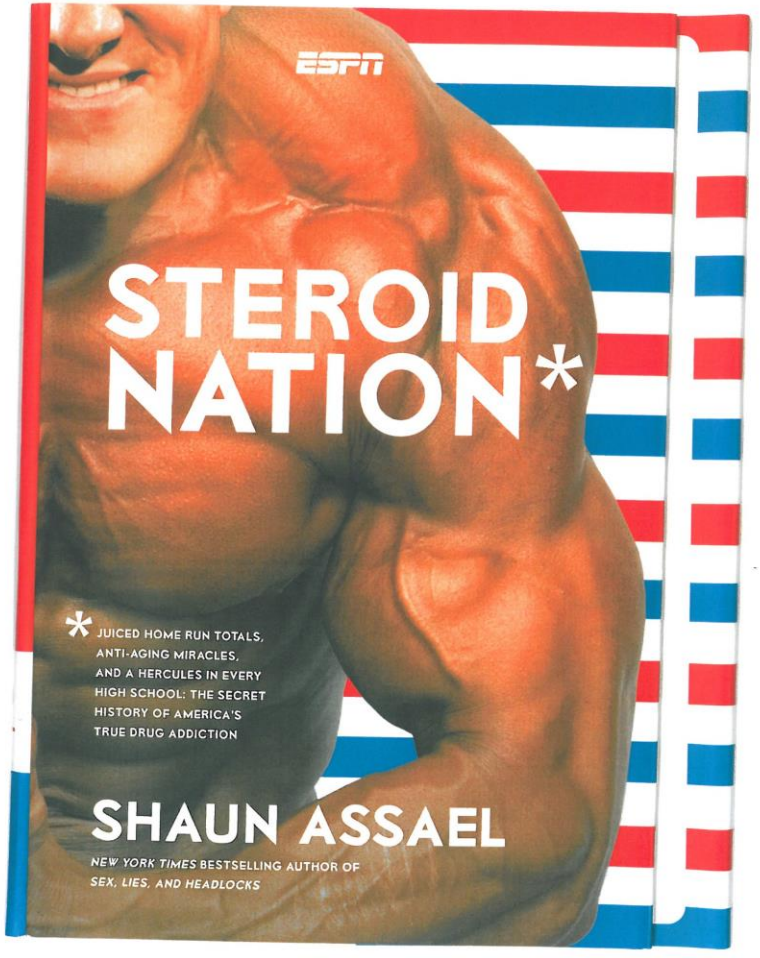
DECEPTION IN WEIGHT-LOSS ADVERTISING WORKSHOP:

Seizing Opportunities and Building Partnerships to Stop Weight-Loss Fraud

A Federal Trade Commission Staff Report

December 2003


ESPN
STEROID NATION*
* JUICED HOME RUN TOTALS, ANTI-AGING MIRACLES, AND A HERCULES IN EVERY HIGH SCHOOL: THE SECRET HISTORY OF AMERICA'S TRUE DRUG ADDICTION
SHAUN ASSAEL
NEW YORK TIMES BESTSELLING AUTHOR OF SEX, LIES, AND HEADLOCKS

federal register

Thursday
February 6, 1997

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Ch. I

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements; Proposed Rule

Distinguished Speakers

...hael Ash, BSc (Hons), DO, ND, Dip ...
...ri-Link Ltd

Debasis Bagchi, PhD, FACN
Interhealth Nutraceuticals, Inc.

Elizabeth A. Beezer
Nicholas Hall & Co.

Charles H. Brain
Ingredient Innovations International

Stacey J. Bell, DSc, RD
Medical Foods, Inc.

John F. Cassens
Cassens Consulting

Mark L. Dreher, PhD
Mead Johnson Nutritionals

Joerg Gruenwald, PhD
PhytoPharm, Consulting,
Institute for Phytopharmaceuticals

Sheldon S. Hendler, PhD, MD
Vyrex Corporation
UCSD
Journal of Medicinal Food

Donald K. Ingram, PhD
National Institute on Aging -
Gerontology Center, NIH

...ert Jones
...dical Foods, Inc.**

James A. Joseph, PhD
The USDA Jean Meyer Human Nutrition Research Center on Aging
Tufts University

Paris M. Kidd, PhD
PMK Biomedical Nutritional Consulting

Antonio C. Martinez II
Antonio C. Martinez II, PC

Earl L. Mindell, RPH, PhD
Author, *The Vitamin Bible, Soy Miracle & Prescription Alternatives*
Pacific Western University

Daniel A. Nadeau, MD
Eastern Maine Medical Center

George Roth, PhD
National Institute on Aging -
Gerontology Center, NIH

Erika Schwartz, MD
Natural Energy- From Tired to Terrific in 10 Days
Internist, Irvington Medical

Julie Smolyansky
Lifeway Foods

...ey A. Zawel, PhD
...ocery Manufacturers of America (GMA)**

John L. Zenk, MD
7-Keto DHEA,
Living Longer in the Boomer Age
International Medicine & Geriatric Associates, Inc.

ANTI-AGING Nutraceuticals:

The 3rd Annual

Dietary Supplements

Functional & Medical Foods

for the Chronic Diseases of Aging

The 3rd Annual Scientific, Marketing & Regulatory Symposium for Preventative Health & Treatment of Aging

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2 TRACKS

SCIENTIFIC UPDATES

- Antioxidants
- The Value of Soy
- Mental Acuity
- New Delivery Methods
- Effects Of Fructooligosaccharides (FOS)
- Biotechnology & Nutraceuticals
- Natural Energy: Preventing Aging

MARKETING STRATEGIES

- Brand Identity
- Multiple Channel Marketing
- Taking An Anti-Aging Product To Market
- Anti-Aging Product Differentiation
- Marketing Case Studies
- Post-Menopausal Market
- Patenting Claims

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2 Leaders in Nutraceuticals Keynotes

Sheldon S. Hendler, PhD, MD
Chairman & Chief Executive Officer **Vyrex Corporation,** & Associate Clinical Professor of Medicine, **UCSD,** Editor in Chief **Journal of Medicinal Food**

John L. Zenk, MD
Author, *7-Keto DHEA, Living Longer in the Boomer Age* & **Physician, International Medicine & Geriatric Associated**

PANEL DISCUSSION

Making Claims:
Treading A Fine Regulation Line

What claims can you place on your labels? Stacey Zawel from the GMA, Antonio C. Martinez II, a Government Relations Consultant specializing in Food & Drug law, and Mark L. Dreher, PhD a Regulatory Director from Mead Johnson Nutritionals will answer all questions concerning the current regulatory environment surrounding the anti-aging nutraceutical arena.

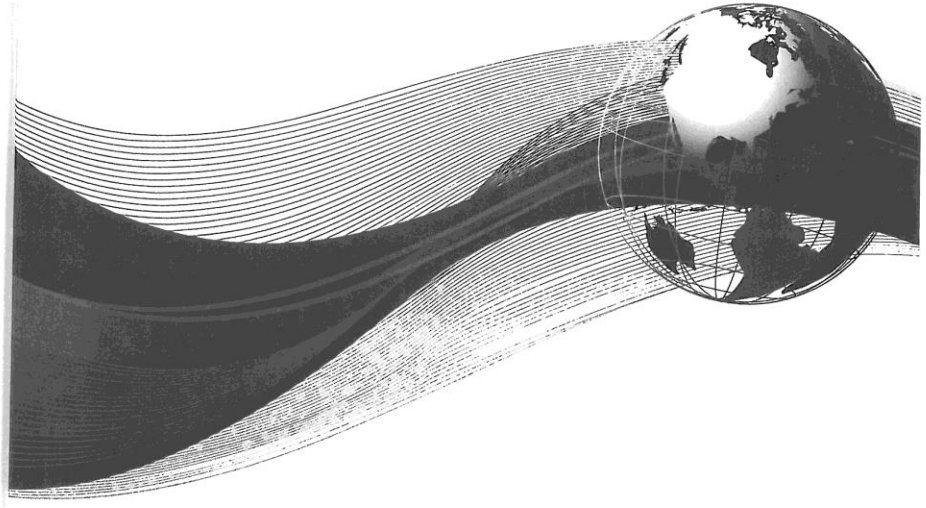
Important Note: Mark your calendar for Nutracon '99

Anti-aging Nutraceuticals should not be confused with our annual NUTRACON conference, an annual review of all the important scientific breakthroughs, marketing and investment strategies for nutraceuticals. Mark your calender for the Sixth Annual NUTRACON event for July 12-14 in Las Vegas!

Global Guide to

The Handling of Adverse Event Complaints

Guidelines for Supplement Companies



IADSA

International Alliance of Dietary/
Food Supplement Associations

According to a recent study, more than 50% of surgical patients took herbs, vitamins, dietary supplements or homeopathic medicines during the 2 weeks prior to surgery.

Over 39 million Americans take dietary supplements on a weekly basis.

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Cedars-Sinai Integrative Medicine Medical Group, Los Angeles, CA

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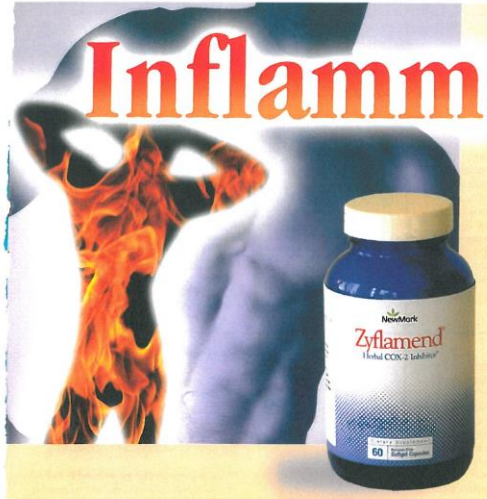
Inflammation?



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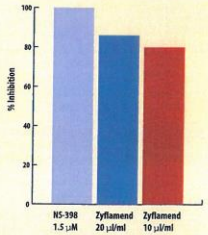
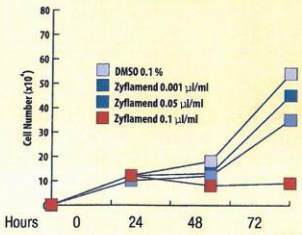
- COX-2 inhibition demonstrated at Columbia University, Department of Urology

Effects of Zyflamend on COX-2*



Zyflamend inhibits COX-2 activity at levels almost equivalent to the specific prescription COX-2 inhibitor, NS-398.*

Zyflamend Affects Cell Growth*



Following 72 hrs of treatment with Zyflamend (0.1ug/ml), a significant reduction (78%) in cell numbers is shown.

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

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engredea

STRATEGIC INFORMATION FOR THE NUTRITION INDUSTRY

Supplement Market Grows to $32.5 Billion

But are stormy skies ahead, thanks to legislative creep & non-GMO movement?

The U.S. dietary supplement market grew to $32.5 billion in 2012, posting more than $2 billion in incremental sales and 7.5% annual growth, but thought leaders and industry insiders suggest that the skies up ahead aren't quite so blue.

"After some even stronger than normal growth in the last couple of years, we expect the sector to revert to a more normalized rate of growth in the 5% range or so," says Scott Van Winkle, managing director of equity research at New York-based **Canaccord Genuity**. "Even with some challenges—whether regulatory challenges such as DMAA or the recent focus on NDIs, or some recent unsupportive research—the sector continues to expand in all channels of trade. We expect further growth and believe that the regulatory environment, while always challenging, is favorable for sustained growth."

Van Winkle points to a number of factors contributing to overall industry growth. "The protein category remains robust and appears to have significantly broadened its scope from sports and weight loss to mass market adoption," he says. "Trends such as cleansing have also driven growth, and the supplement industry is seeing growth in weight loss while many other weight-loss segments are not."

"Brain health is poised to be another exciting segment," he adds. "We continue to look for something big in brain health to become the success story, just as glucosamine/chondroitin or omega-3s exploded into billion dollar categories."

The top hindrance to industry growth continues to be conflicting media reports about supplement research, according to Van Winkle. "It appears to us that the ratio of positive to negative research on supplements has been swinging unfavorably. While there hasn't been a catastrophic study impacting sales trends, as has occurred a few times in the past, we generally believe that the research drives the media and the media drives consumers."

Countering mixed media messages may require an industry-wide effort. "Transparency is the key to trust, and education is the foundation from which that transparency should be built," says Scott Steinford, president of **Doctor's Best Vitamins** based in San Clemente, California. "It's not enough to merely advertise. Both supplement and ingredient manufacturers should partner to provide a more respected and transparent supply chain and then inform the consumer of the same."

FDA's increased enforcement of DSHEA has furthered this concept of transparency—and consumer confidence—especially as it relates to mislabeling, ingredient testing or in-process controls violations, according to Steve Mister, president & CEO

CONTINUED ON PAGE 3


GMP
GMP CERTIFIED CLEANROOM
GMP-STATUS CERTIFIED MANUFACTURER
PHARMACEUTICAL GMP CERTIFIED
SYSTEM CERTIFICATION GMP SGS
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GMP CERT. NO. : XXXXXX
FDA Registered & Compliant Licensed with State of Oregon as a Food Storage/Dietary Supplement Facility!
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GMP
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GOOD MANUFACTURING GMP CERTIFIED Quality Practices
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GMP Good Manufacturing Practice
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FDA
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Good Manufacturing Practice Quality Standard Product
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2019: DSHEA at 25

FDA U.S. FOOD & DRUG ADMINISTRATION

COMMISSIONER

SCOTT GOTTLIEB RESIGNS

New FDA Initiatives

1. Amendments to DSHEA.
2. Regulatory pathway for cannabis.
3. Three focus points:
   - GMP improvements
   - Unlawful claims
   - Spiking

A few industry issues:

- NDI reassessments.
- Inspection consistency.
- Recognize a “no-483” inspection.
- Synthetic botanicals.
- CBD / Hemp Extracts -- status

Where we make progress.

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Thank you!

Loren Israelsen
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