The Marketing of a Food Ingredient – Understanding a System that has Worked for 105 Years

Gary L. Yingling
Food Policy Impact
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Brief Historical Overview

- The Food and Drug Act of 1906
- Federal Food, Drug, and Cosmetic Act of 1938
- Food Additives Amendments of 1958
GRAS Affirmation Regulations
GRAS Notification 1997
What is a GRAS substance?

- Has not been submitted to FDA for a food additive petition
- Marketed based in part on publicly available data
To market a “new” food substance today

- Filing a food additive petition
- Submitting a GRAS notification
- Submission to the Flavor and Extract Manufacturers Association
- Making a self-determination
GRAS Notification
GRAS Notification

- Same level of scientific support as a food addition petition but published
- Additional scientific data that is not published
- Manufacturing information
GRAS Notification

- Use levels
- Human exposure
- Expert panel report (optional)
- Company will provide the supporting data
- Statement by the company that supports a GRAS determination
Information available online

- List of all GRAS notices filed
- FDA no objection letters
Self-affirmation

Why?

- Cost and time
- Substance is so similar to other substances listed as GRAS
Risks of Self-GRAS

- FDA could disagree
- Buyers may not be satisfied
- Substance could cause health concerns
The regulatory system in place works and does not need to be changed.
The NDI Guidance: What to Know to Quickly, Safely and Legally Bring New Dietary Supplements to Market?
New Dietary Ingredients

- **Quickly**
  - 75 day premarket notification

- **Safely**
  - ‘reasonable expectation of safety’

- **Legally**
  - Ingredient must be a ‘dietary ingredient’
  - …FDA does not object
What DSHEA Says…

Sec. 413. [21 USC §350b] New Dietary Ingredients

(a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:

(1) 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.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.
In the past 17 years...

- FDA says there are 1,000 new products a year.
- FDA has “acknowledged” 162 NDI notifications.
- It has objected to 450.
- Yet, in that time, FDA has only issued one warning letter for failing to file an NDI notice, and has never brought an enforcement action on this basis.

Clearly, industry and FDA have different understandings of the NDI requirements.
The NDI Draft Guidance

- Released July 2011
- Represents FDA’s current thinking
  - It is not a law or a regulation
- There is no effective date
  - compliance is expected now
1. FDA says synthetic versions of botanical ingredients are not legitimate dietary ingredients.

- If FDA’s view prevails, “bio-identical” versions of botanical extracts could not be used in dietary supplements. PERIOD!

- **Industry Challenge:**
  - manufacturers use bio-identical synthetics because they are more uniform, more sustainable or more commercially viable than harvesting the plant

- **Opportunity for synthetic components of botanicals?**
  - GRAS, presence in food supply or foreign food supply
2. FDA says the burden to prove an ingredient is “grandfathered” (i.e., not “new”) is on the marketer.

- FDA rejects lists of pre-1994 ingredients and affidavits of mfrs as evidence of pre-1994 sales.
- FDA says companies must produce sales catalogs, invoices, receipts, etc., to prove pre-1994 sale – even older companies may not have these records.
- Newer companies are disadvantaged if they can’t demonstrate pre-1994 sale of an ingredient by another company
  - Take Home: Ask suppliers for evidence of ODI, NDI without notification, or NDIN.
3. FDA says changes in the mfring process of an old ingredient may make it a “new ingredient, subject to the NDI process.

- FDA broadly defines what is “chemically altered” so that changes in extraction and other innovations since 1994 may make old ingredients, long presumed to be safe, subject to additional, burdensome scientific assessment.

- Industry Challenge:
  - This view stifles innovation and increases the costs to bring new technology to market
  - Potential a backlog for industry and FDA alike if all these ingredients required NDI filings
4. FDA says every product that contains a new dietary ingredient requires a separate notice to FDA with a demonstration of safety.

- FDA and the industry disagree on this interpretation of DSHEA

- **Industry position:**
  - DSHEA refers to a “reasonable expectation of safety” of the ingredient, not each product.
  - Ingredient suppliers would not be able to “do the science” for their customers, as each formulation would need a separate NDI notice.
  - Results in redundant notifications for similar products

- Would add costs to industry; potential backlog at FDA.
5. The amount and level of science imposed by the Guidance would treat dietary ingredients almost identically to food additives.

- DSHEA standard for new dietary ingredients is "reasonable expectation of safety" – contrast with the assurance of safety for food additives.
- FDA cites to *Redbook* as authoritative for demonstrating safety of dietary ingredients. *Redbook* is the food additive "bible."
  - *Redbook* requirements may necessitate multi-generational studies, and studies at up to 1,000x the expected dosage.
- Industry Challenge - Requirements are unreasonable with little intellectual property protection – FDA still says in its letters that the NDI review is not a finding that the ingredient is "safe."
- Best practice will be to emphasize all evidence of prior human use of NDI or a substantially similar substance
What optimists are saying

- Reinforces that dietary supplements are a regulated industry
- Provides a roadmap for companies with resources necessary to successfully file NDI notification
  - pre-submission meetings with FDA are an option
- History of safe use and evidence derived from significantly similar substances can reduce the scientific burden of submissions
- GRAS, in the food supply, and not chemically altered
  - no notification required
- Evidence in foreign food supply, not chemically altered
  - no notification required
- Reference to previously successful notifications
“... but it’s only a guidance document”

A Guidance document represents the FDA's current thinking on the topic. It does NOT create or confer any rights for or on any person and does not operate to bind FDA or the public.

- This is a DRAFT guidance with opportunity to comment and influence the agency's interpretations.

Deadline for comments December 2, 2011.

- tomorrow
Why Is the Industry Concerned?

Prior to DSHEA, FDA tried to regulate various dietary supplements like food additives.

Congress rejected that approach with the passage of DSHEA – existing ingredients were presumed safe unless FDA demonstrated otherwise and created the NDI process for new ones.

Now, through the NDI guidance, FDA is imposing requirements for NDIs that are remarkably similar to the standards for food additives....

...and redefining the boundary between “old” and “new” to require more ingredients to go through the NDI process.
What Happens Next?

- Comments period ends tomorrow.
  - Hopefully, FDA will reconsider at least some of its interpretations.

- Legislative and judicial options are possible responses by industry.

- In the meantime, FDA may enforce the Guidance based on its current views without advance notice – detention at port, seizure, recall, warning letters, injunction, etc.

(A Guidance document doesn’t have an effective date.)
Thank you,

Douglas ‘Duffy’ MacKay
Council for Responsible Nutrition
dmackay@crnusa.org
Introducing New Food Ingredients and Natural Health Products to the Canadian Market

Andrea W. Wong, Ph.D.
Senior Scientific & Regulatory Consultant
Food & Nutrition Group
Overview

Novel Foods
• Definitions
• Regulatory process
• Recent updates

Natural Health Products
• Definitions
• Main regulatory components
• Recent updates
• Upcoming changes
Novel Foods

- Foods resulting from a process not previously used for food.
- Products that do not have a history of safe use as a food.
- Foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods.
Novel Process

• A food that has been manufactured, prepared, preserved or packaged by a process that:
  (i) has not been previously applied to that food, and
  (ii) causes the food to undergo a major change.
Major Change means a change in the food that places the modified food outside the accepted limits of natural variations for that food with regard to:

a) The composition, structure, or nutritional quality of the food or its generally recognized physiological effects.

b) The manner in which the food is metabolized in the body.

c) The microbiological safety, the chemical safety, or the safe use of the food.
• A food that is derived from a plant, animal or microorganism that has been genetically modified such that:

  (i) The plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism.

  (ii) The plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism.

  (iii) One or more of the characteristics of the plant, animal or microorganism no longer falls within the range of for that plant, animal or microorganism.
Regulatory Process for Novel Foods

- Pre-market notifications should contain the following information:
  - Chemistry and manufacturing
  - Intended use/use-levels and resulting dietary exposure
  - Safety
  - Nutritional impact
- Health Canada conducts a pre-market assessment.
- Applicants receive a letter of no objection authorizing the sale of the novel food.
Recent Update: Priority Scheduling and Expedited Handling

• Policy for moving eligible food additive submissions, food irradiation submissions, and novel food submissions through the evaluation and authorization phases more quickly.

• Applies only to substances / technologies that have a demonstrated capacity to enhance the microbiological safety of food.

• For novel foods:
  • Verification within 7 days
  • Screening within 45 days
  • Review of submissions within 45 days
Natural Health Products (NHPs)

• Defined according to substance and function:

  • **Substance**
    • Ingredients with natural origin and/or their synthetic duplicates.
    • Does not include drugs with prescription status (*i.e.*, ingredients listed under Schedule F of the Canadian Food and Drugs Act).

  • **Function (claims)**
    • Allows for use of therapeutic, risk-reduction, and structure function claims with appropriate evidence of efficacy.
Main Regulatory Components

• Product Licences
  • Required for all NHPs sold in Canada.
  • 4 Different types, depending on product
    • Pre-cleared information (PCI)
    • Traditional claims
    • Non-traditional claims
    • Homeopathic medicines
  • Evidence requirements for safety and efficacy dependent on type of application.
Natural Health Product Master Files (NHP-MF)

- Applications may reference an NHP-MF for supporting evidence of an ingredient or blend of proprietary ingredients.
- NHP-MFs are specific to an ingredient or proprietary blend of ingredients.
- Submission includes proprietary or publicly available data supporting quality, efficacy, and/or safety.
- A file and submission number issued for each NHP-MF
  - Subject to confidentiality.
  - NHP-MF number and access letter must be provided to finished product manufacturers for cross-referencing within a PLA.
- Only reviewed in conjunction with referencing PLA.
- NHP-MF never approved or rejected.
Recent Updates: Natural Health Products Ingredients Database (NHPIID)

- Confirms that the substance can be classified as an NHP ingredient and that labeling is consistent across all NHPs.
- Inclusion within the NHPIID does not mean that the ingredient is approved for use in NHPs.
- Evidence supporting the safety and efficacy of the medicinal ingredient in accordance with its conditions of use will be required when submitting a PLA.
  - Evidence may include PCI, publicly available literature, proprietary data submitted as part of a Natural Health Product Master File (NHP-MF).
**Recent Updates: Probiotics and Enzymes**

- New PCI for probiotics and enzymes released September 2011.
- **Probiotics Monograph**
  - Includes only health claims based on strain-specific evidence for selected bacteria and yeast.
- **Abbreviated Labelling Standard (AbLS) for Live Microorganisms**
  - Supports the claim “temporarily modifies gut flora”.
- **AbLS for enzymes**
  - Use of enzymes acceptable for occasional use.
  - Maximum duration of use is 3 days, unless otherwise stated in the AbLS.
Upcoming Changes (Cont’d)

- **Energy drinks** will be regulated as foods instead of NHPs.
  - Will be subject to new composition and labeling requirements.
- Re-classification of 11 Ingredients currently listed as prescription drugs (**Schedule F**) expected in November 2011.
  - Includes ingredients such as L-carnitine and L-tryptophan.
- Recommendations for **Weight Loss Claims** to be published within the Standards of Evidence (SOE) guidance document.
Upcoming Changes

• Several other guidance documents and updated PCI (20 documents) expected by end of 2011 to beginning 2012.
  • PCI for Energy drinks in small dosage formats (Oct/Nov 2011).
  • SOE for combination of medicinal ingredients (Dec 2011).
  • Revised Quality Guidance Document (Dec 2011).
  • Single and multi-vitamin monographs (Jan/Feb 2012).
• Compliance and Enforcement activities remain on hold until release of SOE Guidance Document.
  • No expected date of implementation.
Summary

Novel Foods

• Pre-market notifications are required for foods produced by a novel process, foods without a history of safe use, and genetically modified foods.
Natural Health Products

• Pre-market approval is required for all finished products.
  • Ensure that all ingredients contained in the NHP are listed within the NHPID before submitting a PLA.

• Ingredient manufacturers can submit NHP-MFs in support of a PLA.

• Numerous upcoming changes to PCI, guidance documents, and classification of ingredients/products expected between October 2011 and February 2012.
Thank you!

awong@cantox.com

905-286-4135