

**American Herbal Products
Association**

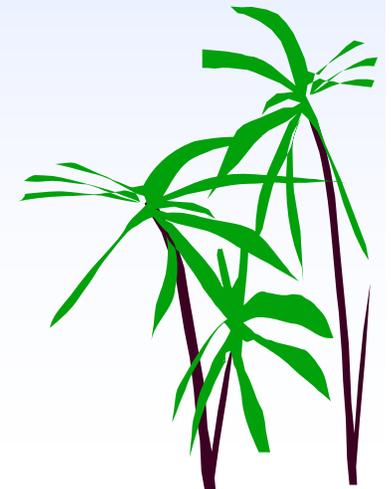
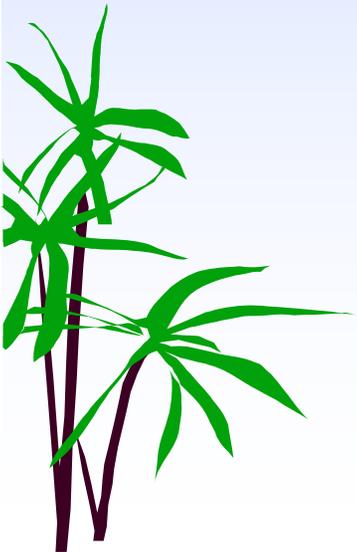
“Functional Foods”

**Can and Should Meet Present
FFDCA Requirements
and Added Caffeine Should be
Labeled**

Anthony L. Young

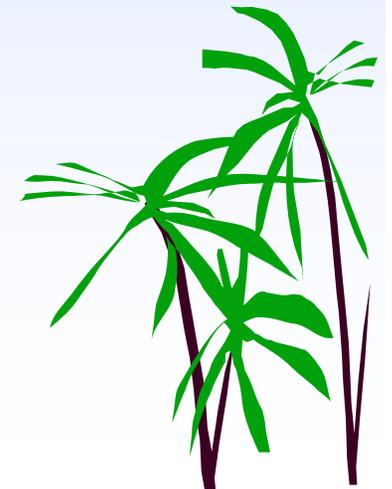
General Counsel

**American Herbal Products
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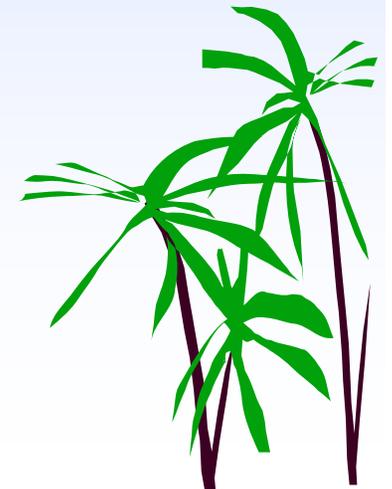
Functional Foods Historically

- Iodized salt
- Coffee and Black Tea
- Caffeine containing soft drinks
- Infant formula and foods
- Adult liquid meal replacements
- Prunes and prune juice
- Breakfast cereals fortified with vitamins and minerals
- Weight maintenance and reduction foods
- High fiber foods
- Electrolyte replacements
- Fortified grain products



Uses of Historical Functional Foods

- **Function alone**
- **Nutrition and function**
- **Hydration and function**
- **IFT definition of “foods that provide a health benefit beyond basic nutrition” appears to encompass all these historical functional foods**



Present Law is Adequate for These Types of Food

- **Food Additive amendments with GRAS self-affirmation or GRAS notification address ingredient safety**
- **Label claims must be truthful and not misleading and not fail to reveal material information**
- **Health claims must be cleared through FDA or notified to FDA if based on authoritative determination**



GRAS Substances in Food

- § 402(a)(2)(C): Food is adulterated if it contains an “unsafe” food additive, one not covered by an FDA regulation, OR
- the substance is GRAS through common knowledge of scientific information throughout the scientific community
- Reasonable certainty that the substance is not harmful under the specific intended conditions of use – (reasonable certainty of no harm)



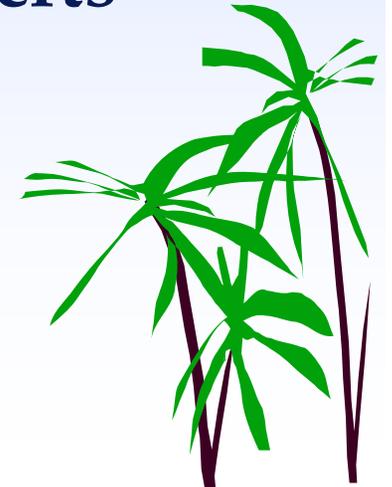
GRAS Ingredients Conditions of Use

- GRAS notifications must list the foods for which the ingredient is intended.
- 43 categories from baked goods to sweet sauces. 21 CFR Sec. 170.3
- Must describe and list proposed amounts for each category of food selected.
- Many food ingredients are not GRAS for all uses and are not intended to be GRAS for all uses



General Recognition of Safety of a Novel Food Ingredient

- Scientific Procedures
 - Generally available and accepted scientific data
 - Ordinarily published
 - Corroborated by unpublished data
 - Normally reviewed by panel of experts
 - OR
- Common use in food prior to 1958



GRAS Self-Affirmation

- GRAS self-affirmation or GRAS notification is a predicate for the use of a novel ingredient in food
- Panel of Experts review safety and their conclusion is important to prospective food manufacturer customers.
- No notification or review by FDA is required of a GRAS self-affirmation
- Important risk averse food manufacturer customers may not accept GRAS self-affirmation for an ingredient



FDA GRAS NOTIFICATION PROCESS AND WEBSITE

- Present count – 213 notifications
- Roughly 10 % pending
- Roughly 12 % withdrawn
- 5 % resubmitted, most successfully
- Roughly 75 % FDA has no questions
- Roughly 8% do not provide a basis for a GRAS determination
- GRAS notification system WORKS and it WORKS WELL.



GRAS Notification Process

Novel Ingredients

- Novel ingredients are often not intended to be added to a wide variety of foods.
- Novel ingredients may require limitations on use by certain classes of persons.
- For food additives, safety limitations are addressed by cautions; aspartame and phenylketonurics,
- GRAS self-affirmation or notification can be made to include “any labeling that will be required by applicable provisions of the FFDCFA on the finished food”



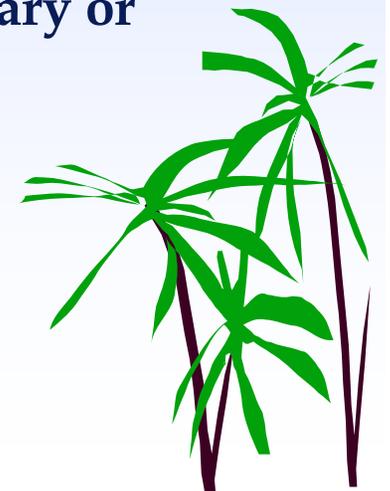
Novel Ingredient Safety Review

- GRAS reviews for novel ingredients should be based on specific limitations on use, e.g., adults only, or to specific limitations on use, e.g., consume no more than one gram of “novel” from any source per day.
- Failure to carry Cautions or Warning raises the issue of false or misleading labeling and this can be addressed in GRAS self-affirmation or GRAS notifications.



21 U.S.C. Sec. 201(n)

- n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual



AHPA Recommends

- No new “functional food” category
- GRAS self-affirmation or GRAS ingredient notification should work for novel ingredients for limited food use
- Use FFDCA food labeling provisions and Section 201(n) to assure proper labeling of limited food use novel ingredients
- Establish voluntary food claims notification process that parallels GRAS ingredient notification process for those who want added assurance of FDA review
- Label added caffeine in package form food



CAFFEINE

- If the concern is mainly beverages, is the issue really about caffeine?
- Caffeine is a medicinal ingredient found in many plants and an ingredient that is added to food
- AHPA recommends in its Code of Ethics & Business Conduct that the amount of caffeine, if above 25 mg. per serving be declared on the labels of dietary supplements
- AHPA recommends the labeling of added caffeine above 25 mg. per serving in package form food.



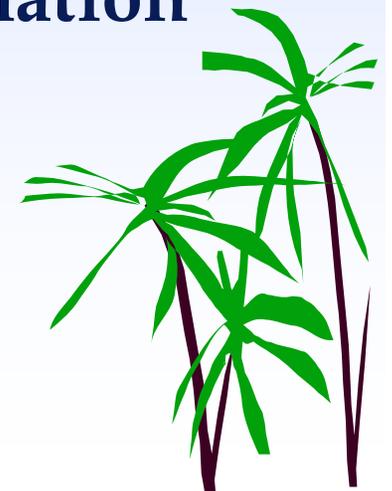
CAFFEINE

- <http://www.energyfiend.com/the-caffeine-database/>
- Describes caffeine amounts in beverages.
- <http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202105.html>
- Describes the health effects of caffeine



CAFFEINE

- Medline Plus says:
- It is recommended that pregnant women consume less than 300 mg of caffeine a day.
- Caffeine passes into breast milk in small amounts and may build up in the nursing baby.
- FFDCA Section 201(n) material information for Moms – why NOT require added caffeine to be labeled?



Conclusion

- **AHPA recommends FDA use current law to address the use of novel ingredients in so-called functional food, no new system is required.**
- **AHPA recommends FDA initiate rulemaking to require the amount of caffeine added to food to be labeled.**



THANK YOU

**American Herbal
Products Association**

