



CENTER FOR
Science IN THE
Public Interest

The nonprofit publisher of
Nutrition Action Healthletter

1357 7 13-6 9 51

February 6, 2007

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852

Re: Docket Number 2002P-0122, Conventional Foods Being Marketed as "Functional Foods"

To Whom It May Concern:

Please accept these comments for filing in Docket Number 2002P-0122, Conventional Foods Being Marketed as "Functional Foods." They are an extended version of a presentation given by Ilene Ringel Heller at the Public Hearing on October 25, 2006.

Thank you for your assistance.

Sincerely,



Hilary Kennedy

2002P-0122

C3

Substances in Food and Labeling; Regulatory
Framework for Foods that Companies are
Marketing as “Functional Foods”

Public Hearing Before U.S. Food and Drug
Administration

Ilene Ringel Heller

Senior Staff Attorney

Center for Science in the Public Interest

December 5, 2006

Question 3: FDA Should Issue Pre-Notification Regulations for Novel Ingredients

FDA has rulemaking authority under Section 701(a) “for the efficient enforcement of this Act.”

Safety:

- Pre-market notification will ensure that all added ingredients are GRAS.
- Some structure/function claims could cause consumers to delay seeking appropriate medical care before a problem worsens.

Labeling

- Standardized terminology ensures that consumers are not misled.
- FDA will have opportunity to require any necessary instructions for use of warning labels before problems arise.

Question 4: IFT Recommendation to Establish GRAS Review Panels is Unlawful and Unnecessary

- “Functional foods” is a popular term for products already regulated by statute.
- Safety and efficacy issues are addressed by FDCA provisions for:
 - Food Additives
 - Health Claims
 - Structure/Function Claims
 - Drugs
 - Misbranding.

FDA Has Sole Authority to Determine Appropriateness of Ingredients and Claims

- Food Additive petitions must be approved by FDA.
- Health Claims must be authorized by FDA.

FDCA Specifies When Outside Experts Can be Used for Health and Nutrient Content Claims

- FDAMA – permits manufacturers to rely on “authoritative statements” from expert **governmental** bodies as support for proposed claims.
- FDA ultimately decides whether to rely on “authoritative statement” as the basis for approving a claim.

The Law Permits FDA to Consider Recommendations of Advisory Committees

- FDA is permitted to create advisory committees.
- FDA routinely considers the recommendations of advisory committees when approving drugs.
- FDA already has a Food Advisory Committee.
- NAS-DESI review of efficacy.

Question 5: IFT Recommendation to Modify Definition of Nutritive Value is Contrary to Law

- Pre -1938, only products making disease claims were considered to be drugs.
- Problem: Slenderizers making misleading claims for obesity, but at time, obesity was not considered to be a disease.
- 1937: FTC brought case against Raladam Co., which was marketing Marmola tablets containing half a gram of dessicated thyroid to treat obesity or reduce weight. This was very dangerous for those with various ailments. Side effects of long-term use included: rapid pulse, tremors, sweating and diarrhea.

Solution 1938

- Congress expands the definition of drug to include claims to affect a structure or a function of the body.
- But Congress carves out **narrow** exception to permit claims of physiological benefits for foods *that would be consumed ordinarily*.

1958 Amendments Give FDA Additional Labeling Authority to Regulate Safety and Labeling

- Food additives – any substance that can reasonably be expected to become a component of food or otherwise affect the characteristics of any food, e.g. packaging materials, processing aids.
 - Nonnutritive ingredients must have technological effect in the food.
 - Section 402(d): Congress specifies that **nonnutritive** item can be added to confectionery.

Bottom Line: Statute does not give FDA the authority to permit nonnutritive ingredients to be added without express statutory authorization.

Nutritive Value Essential

- *Nutrilab v. Schweicker*: Court concludes that starchblocker tablets found in raw kidney beans are a drug. Court ruled that pills are not a food because they are not consumed **primarily** for taste, aroma or nutritive value.
- Examples of food eligible for s/f claim: coffee, prune juice.

- American Home Products: Starchblockers are not foods. Congress wanted to permit representations for products **primarily** consumed as a food that – secondary to their taste, aroma or nutritive value – provide physiological effects.
- Starchblockers are “utterly useless for any food purpose.”

DSHEA Had Not Yet Been Passed

- S/F exception for foods rarely used until after 1994, when DSHEA permitted supplements to make s/f claims, and the food industry began to see the profitability of such claims.
- Nutritive value still essential to maintain statutory distinctions between food and drugs.

Question 6: IFT's Recommendation That Economic Incentives are Needed to Promote R & D for Functional Foods Ignores Existing Incentives

- Rising Sales – Sales of functional foods have increased from \$16.2 billion in 1999 to \$24.3 billion in 2004 – a 50% increase – *without economic incentives.*

Source: *Nutrition Business Journal*



Technological Advances

- The improved ability of food processors to mask the unpleasant tastes of ingredients such as Omega-3 fatty acids from fish oils demonstrates that strong incentives already exist to develop such products.

Exclusivity Contrary to Statute

- None of the other statutory food safety and labeling approval measures provide exclusivity to the petitioner: food additive regulations, health claims or nutrient content claims.
- There is no scarcity in the marketplace of products bearing health claims, nutrient content claims or structure/function claims.

Government Funding for Research Needs to be Increased

- Contracts should be awarded to NIH to research the safety and efficacy of the most widely used ingredients.

Question 7: Are Existing Regulations Adequate?

- FDA has adequate legal authority to regulate functional foods. No specific definition is required because such foods already fall into particular regulatory categories that will ensure that products are safe and that labels are not false or misleading.
- What is needed is pre-notification of novel ingredients and adequate enforcement.

Question 7: Enforcement Efforts Are Inadequate

- Food labeling is only reviewed as part of a risk-based safety inspection, once every five years.
- FDA is making some progress against illegal claims on the web – e.g., in one effort, FDA sent warning letters to 29 cherry juice companies with products claiming to treat or prevent cancer, heart disease or arthritis.



Increased Enforcement Essential

- We located warning letters for only five functional food companies that were issued as a result of plant inspections or review of product labels.
- Illegal nutrient content claims abound where a qualified health claim has been authorized, e.g., omega-3 fatty acids, green tea.
- FDA should authorize health claims and nutrient content claims in tandem.

Illegal Medical Foods

- Some “functional” foods masquerade as medical foods in an attempt to escape requirements for conventional foods.
- ANPR issued in 1996 (withdrawn in 2003).
- FDA should crack down on phony medical foods.



FDA Action Needed

- Each district office should designate functional food inspector.
- Functional food inspector should conduct field examinations in supermarkets to detect questionable products.
- CFSAN should designate staffer to review web ads and popular self-help or body building publications for suspicious products.

Inspections Should Be Targeted At Functional Food Manufacturing Facilities

- Labeling is given only a cursory review during safety inspections.
- Inspectors are told not to do critical labeling reviews unless they have specific authorization.
- Inspectors are told not to look at more than 3 labels per inspection.

Enforcement Actions Should be Well Publicized

- Well publicized enforcement actions can persuade the rest of the industry to halt misleading and potentially harmful claims.