

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 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 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: 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.

# CocoaVia<sup>®</sup>

Heart Healthy Snacks

BRAND



- Formulated to Help
- ♥ Reduce Bad Cholesterol
  - ♥ Promote Healthy Circulation

1.0 OZ PACK (5.0 OZ) 28.4g PACK (1.42g)

CHOCOLATE COVERED  
ALMONDS

5 Individually  
Wrapped Servings

# 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.