

1 Breaking Down the Barriers to Functional Foods

FDA Public Meeting

December 6, 2006

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2 Functional Food Players and the Impasse

3 Four things FDA must do to resolve the impasse

1. Create a new category of functional claims
2. Promote the use of Independent Expert determinations
3. Initiate a notification system
4. Provide a term of exclusivity and ROI for manufacturers

4 1. Health to Functional Claims

Provides health a benefit beyond basic nutrition.

We have found the "no brainers" and those for whom cost was no object

- *Vitamin C – scurvy*
- *Thiamine (B1) – beri beri*
- *Iodine – goiter*
- *Calcium - rickets*
- *Calcium and osteoporosis – 101.72*
- *Sodium and hypertension – 101.74*
- *Dietary fiber and cancer – 101.76*

5 1. Health to Functional Claims

To move forward FDA must

- a. Disconnect health-disease conundrum
- b. Allow claims based on changes in biomarkers
- c. Allow claims for specific population subsets
- d. Most of all *be flexible*

6 1. Health to Functional Claims ***Time now for the tough choices***

- May include a substance *unrecognized* by "mainstream" science (e.g. folate)
- *Unrecognized* as the result of the objections of political interests
 - Pharmaceutical lobby
 - Insurance (& Medicare) limitations
 - Research foundations and grant recipients

7  **1. Health to Functional Claims *Time now for the tough choices***

- Nutrigenomics options
 - Proteomics
 - Metabolomics
- Special subpopulations with special needs

Because the ingredients are in food - all ingredients must be safe for any consumer

8  **2. Independent Experts**

- Precedent
 - GRAS for food ingredients
 - GRASE (...*safe and effective*) for drugs
 - FDA Advisory Committees
- Fact Sheet – Strategy for Dietary Supp.
 - Third party review cited

9  **3. Notification Program**

- Examples
 - GRAS Notification
 - NDIN
 - Qualified Health Claims
- Advantages
 - Public information and safety
 - Assured vendors

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14  **4. A term of Exclusive Marketing Rights**

- Precedent
 - Food additive master files
 - Drug master files
- Will drive investment
 - Fund safety studies
 - Fund efficacy studies
- Return on investment required

15  **Term of Exclusivity**

1 Public Release
(immediate)

- Safety information
- Claim
- Product name & manufacturer

2 Sequestered Info.
(~5 years)

- Supporting evidence for claim

16 4. Term of Exclusivity

17 4. Term of Exclusivity

18 4. Term of Exclusivity

19 Four Steps Forward

1. Change from health claims to functional claims
2. Promote the use of Independent Experts
3. Initiate a Notification program
4. Permit a term of exclusivity for ROI

20 Resolution

- Consumers
 - Empowerment - greater access to new discoveries/enhancement of QoL
 - Drug cost savings
- Industry
 - Free speech assured
 - Return on investment
- FDA
 - Ensure consumer safety
 - Ensure efficacy (no mis-labeling)
 - Forestall increasing abuse of medical foods category

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