

An IFT Expert Report Functional Foods: *Opportunities and Challenges*
The Key Points from IFT's Comments at the Dec. 5, 2006 FDA Public Hearing on
Marketing Functional Foods

1. IFT Expert Report on Functional Foods was written by an 18-member independent Expert Panel; members chosen based on scientific, medical, and legal expertise.
2. IFT Expert Report definition of functional foods: Foods and food components that provide a health benefit beyond basic nutrition (for the intended population).
3. New science disciplines (i.e., nutrigenomics, proteomics, metabolomics or metabonomics, bioinformatics, etc.) require updated policies and regulations.
4. Existing terminology and regulatory frameworks limit the scope and understanding of consumer information. For example, wording of claims designed to avoid drug classification may inaccurately convey the actual effect of the food or result in misleading statements of the underlying science.
5. Existing terminology and regulatory frameworks hinder the development and marketing of functional foods.
6. Definition of nutritive value needs to better reflect current science by basing health claim benefits for functional foods on “nutritive value or through the provision of a physical or physiological effect”, provided that the effect has been scientifically documented.
7. The IFT Expert Panel supports Qualified Health Claims; however, wording of qualified health claims should clearly indicate the degree of scientific support or certainty associated with a biological effect or modification of disease risk.
8. IFT recommends that FDA policy should not require claims about health effects of foods on normal health structure or function of the body to be based on the limited concept of nutritive value.
9. IFT recommends that FDA base health claims on broad-based scientific criteria that addresses underlying links between health and nutrition, and meets the need for sound scientific substantiation.
10. The IFT Expert Panel recommends that product labeling be allowed to accurately reflect the scientific evidence.
11. IFT is encouraging the implementation of a process that is parallel to GRAS for efficacy determinations that would involve the convening of a panel of independent experts. The expert would determine efficacy pertaining to the

functional food, e.g. to confirm that it is generally regarded as efficacious (GRAE).

12. The IFT Expert Panel recommends that FDA prohibit claims relying on “very limited and preliminary studies” and develop guidelines that protect consumers from limited scientific information.