



FDA Public Hearing: “Conventional Foods” marketed as “Functional Foods”

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Supplements and Functional Foods

- **Keep DS out of the FF regulatory discussion**
- **DSHEA-like Balance: Broad Access with Consumer Protection**

Don't Over Regulate

- **Tools are Currently Available: Stronger enforcement of Current Food Safety and Fraud Laws (i.e. 403(a) FTC section 5 and FDA misbranding provisions)**

Don't Over Regulate

- **Rational Guidance and Further Discussion Needed: Intended Use (Conventional Food v. Supplement), Food Matrix (i.e. Water) and Ingredient Concentration/ Serving Size**
- **Efficacy/GRAE is best dealt with by self-regulation**

Nutrilab v. Schweiker

- **20+ year old decision is basis for limiting structure/function claims**
- **Expand to more than Nutritive Value**

Nutrilab v. Schweiker

- Future movement towards a rational approach to Structure/ Function Claims, Pearson allowed QHC (NLEA/SSA) on foods through 1st Amendment

Good Manufacturing Practices (GMP)

- Where do products containing “Supplement” Ingredients in “Conventional Foods” reside?
- Guidance on Manufacturing for Medical Foods and Infant Formula on Compliance Page

Science

**The Industry Understands that
the Absence or Presence of
Borrowed Science, does not
ensure a Successful or
Unsuccessful Product or
Process**