

*FDA Regulation of Dietary Supplements:
Performance-Enhancing Products*



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FDA Authority to Regulate Dietary Supplements



- Food, Drug & Cosmetic Act
- 1994 Amendments: Dietary Supplement Health & Education Act (DSHEA)
- Labels and labeling

Issues

- What fits the definition of a dietary supplement
 - Terms from statute
 - Considerations of “intended use”
- Safety
 - Post-marketing effort / Adverse event system
 - To remove from market
 - Burden of proof re: “being unsafe” (significant or unreasonable risk)
- Fraudulent claims

DSHEA: Forms of Dietary Supplements



- Pill, capsule, liquid, powder, caplet, etc.
- But also may be in conventional food form

DSHEA: Dietary Supplement Definition

...a product ... intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- vitamin, mineral, or amino acid
- herb or other botanical
- dietary substance
- concentrate, metabolite, constituent or combination

Examples of Dietary Ingredients

vitamin, mineral, amino acid:

- Vitamin C, Carnitine

herb or botanical:

- Echinacea

dietary substance:

- Not yet clearly defined: ??? bee pollen

concentrate, metabolite, constituent:

- Not yet clearly defined: ??? melatonin

What Are Hormones?

Unclear --- Drug or ? perhaps a dietary supplement

– It depends on “intended use”

- If anabolic – Drug ; DEA/Schedule III
- If precursor to Schedule III (e.g., GBL) -- Drug
- If “street drug” alternative – Drug
- If “non-anabolic” for body-building (struc/func – ‘androgenic’)

– Is it a dietary ingredient intended to supplement the diet?

– DSHEA does not address; No legislative history

– FDA has taken no position

– ?Androstenedione, ?DHEA

Safety of Dietary Supplements

- Pre-market determination is largely role of manufacturer
- FDA's responsibility is to remove unsafe ingredients or products from the market
 - Demonstrate significant or unreasonable risk
 - Reliance on passive adverse event system

Safety Concerns: P-E Dietary Supplements

- Paucity of data, esp. for chronic use
- Marketing/use by children and adolescents
- Combinations of ingredients may have adverse consequences
- Exercise may change body's response
- Suggestion that some contain banned substances

Claims Concerns: Fraudulent/Misleading



- Limited resources: “Safety First”
- Claims about effects
- Claims about “proven” safety or “natural” alternatives
- Commitment to address these

Collaborative Effort



- FTC: fraudulent claims
- NIH: effectiveness
- DEA: illicit substances

Needs



- Clarification of definitions
- Research – esp. in view of post-marketing world
- Reporting of adverse events