

CARNITINE

Workshop

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DSHEA

(Dietary Supplement Health and Education Act - 1994)

- **Amended the FD & C Act**
- **Defined dietary supplements**
- **Established regulatory framework**
 - **Food and Drug Administration (FDA)**
 - **As foods, not as drugs**
- **Established rules for what a label should contain**
- **Gave FDA authority to write GMP**
- **Called for creation of the Office of Dietary Supplements at the NIH**

Definition of Dietary Supplement

- ◆ A product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - ❖ A vitamin, mineral, amino acid, herb or other botanical; OR
 - ❖ A dietary substance for use to supplement the diet by increasing the total dietary intake; OR
 - ❖ A concentrate, metabolite, constituent, extract, or combination of any ingredient described above.

Dietary Supplement

- **Intended for ingestion in the form of a capsule, powder, softgel, or gelcap**
- **Not represented as a conventional food or as a sole item of a meal or the diet**
- **Excludes items that are smoked or administered sublingually**
- **Label claims generally limited to effects on a structure or function of the body**

Examples of Ingredients in the Dietary Supplement Category

- Vitamins, minerals
- Antioxidants
- Creatine, **carnitine**
- Lutein, lycopene, phytoestrogens
- Soy, garlic
- Omega-3 fatty acids
- St. John's wort, echinacea, ephedra
- Androstenedione, DHEA
- Combinations



GINKGO - Enhances Memory*

VITAMIN E - For the Heart*

CoENZYME Q10 - Boosts Energy*

ST. JOHN'S WORT - Enhances
Mood and Temperament*

GLUCOSAMINE - For Healthy Joints*

* This statement has not been
evaluated by the FDA. This product
is not intended to diagnose, treat,
cure or prevent any disease.

ODS Mission Statement

The mission of the ODS is to strengthen knowledge and understanding of dietary supplements by **evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public** to foster an enhanced quality of life and health for the U.S. population.

Evidence-Based Review Program

- **Systematic review of the literature, with meta-analysis as appropriate, on DS efficacy and safety**
- **Major reason for conducting these reviews is to assist NIH in the development of an appropriate research agenda**

Omega-3 Fatty Acids



or



Photo of Menhaden courtesy of National Oceanic and Atmospheric Administration (NOAA)

Health Effects of Omega-3 Fatty Acids

- **Systematic review of the literature, with meta-analysis as appropriate, on omega-3 fatty acid supplementation for a number of health indications (prevention of heart disease, immune function enhancement, others)**
- **A series of evidence reports are being developed over 2 years; first ones to be released in April 2004**
- **The major reason for conducting this review is to assist NIH in the development of an appropriate clinical research agenda that will address future questions**

Issues in Conducting Efficacy Research on Dietary Supplements

- **Cost**
 - Federal investment, partnership
- **Quality of Product/Intervention**
 - Characterization, reliability
- **Endpoints/Markers**
 - Effect sizes generally small
- **Generalizability of Results**
 - Diseased vs. healthy population