Dietary Supplements

Purpose

The purpose is to outline the policy and procedure for dietary supplements used in human research.

Definition

According to the Dietary Supplement Health and Education Act (DSHEA) of 1994, a *dietary supplement* is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Some examples are ginseng, garlic, fish oils, psyllium, enzymes or combinations of these. Dietary supplements can be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also appear in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement.

Policy - Regulations Involving Dietary Supplements

While the Food and Drug Administration (FDA) regulates dietary supplements, it does so under a different set of rules than those covering prescription and over-the counter drug products. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, the manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The FDA is responsible for taking action against any unsafe dietary supplement product *after* it reaches the market. Generally, manufacturers do not need to register their products with the FDA nor get FDA approval before producing or selling dietary supplements. Many studies involving the ingestion of dietary supplements may not be subject to FDA oversight. In contrast, if a researcher proposes to study a dietary supplement with the **intent of diagnosis, cure, mitigation, treatment or prevention of disease in**

humans (e.g., hope of reducing medication with use of the supplement), the supplement would be need to be treated as a drug and would be subject to FDA oversight. In such a case, the manufacturer or researcher would need to submit an Investigational New Drug (IND) application to the FDA.

In cases where it appears that a supplement may be used as a "drug," the Principal Investigator must submit an Investigational New Drug application to the FDA. The FDA's determination will need to be submitted to the IRB.

Studies involving the ingestion of dietary supplements that are not subject to FDA oversight are still covered by Office of Human Research Protections (OHRP) regulations, and therefore must be reviewed by the Institutional Review Board (IRB).

Procedure - Investigator's Responsibilities

The investigator is responsible for providing the Institutional Review Board with appropriate information concerning the supplement, such as:

- Ensuring that s/he has done extensive research to ascertain whether the study substance is subject to FDA IND regulations. If it is, regulations need to be followed. http://www.fda.gov/;
- Providing available evidence of use of the substance in humans and/or animals in previous research studies;
- In the case of "medicinal" herbs, providing evidence regarding methods of cultivation and processing (purity, consistency, potency, etc.);
- Performing a health history/screening of potential participants to reduce risks and exclude those at high-risk;
- Stating all possible side effects, including frequency of occurrence, especially for serious side effects.
- In some cases, providing evidence that the supplement sponsor or the PI has consulted with the FDA for advice about need for an IND.

The IRB may seek consultation with a pharmacist or pharmacologist to obtain needed expertise about potential drug and herb interactions.

History

7/9/2013 - Format Updated

9/3/2015 - Updated (IND Exemption Inquiry information)

1/31/2017 - Updated policy based on FDA communication concerning IND requirements

9/28/2017 - Removed information about IND exemption, as FDA has stated that supplements do not qualify.