**1. What is a Dietary Supplement?**

There are numerous preparations that are marketed in the U.S. as dietary supplements.  The definition of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) of 1994 includes:

* A dietary supplement is a product taken by mouth that is intended to supplement the diet and that contains a dietary ingredient.
* 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.
* Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids or powders.

Under DSHEA, a dietary supplement is not considered a drug and is not subject to the premarket approval requirements for drugs if the intended use for which it is marketed is only to affect the structure or any function of the body (i.e., not intended to be used for a therapeutic purpose).

**2. If a dietary supplement, which is available without a prescription, is used in a research study, is an IND needed?**

Whether an IND is needed for a clinical investigation evaluating a dietary supplement is determined by the intent of the clinical investigation. If the clinical investigation is intended only to evaluate the dietary supplement’s effect on the structure or function of the body, an IND is not required. However, if the clinical investigation is intended to evaluate the dietary supplement’s ability to diagnose, cure, mitigate, treat, or prevent a disease,an IND is required under part 312.

For example, a clinical investigation designed to study the relationship between a dietary supplement’s effect on normal structure or function in humans (e.g., calcium and bone mass) or to characterize the mechanism by which a dietary supplement acts to maintain such structure or function (e.g., fiber and bowel regularity) would not need to be conducted under an IND. However, a clinical investigation designed to evaluate a dietary supplement’s ability to prevent osteoporosis or to treat diarrhea or constipation would need to be conducted under an IND under part 312.

See FDA Guidance [IND Determination](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) for further information.

**3. How is it determined if the dietary supplement is being used as a drug?**

The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease".

If a lawfully marketed dietary supplement is studied for its effects on diseases in the proposed investigation (i.e., to cure, treat, mitigate, prevent, or diagnose disease including its associated symptoms), then it is considered an investigational new drug and will be subject to IND requirements.

**4. If a study is evaluating the uses of dietary supplement as dietary supplements is an IND required?**

No.  When a lawfully marketed dietary supplement is studied for its dietary supplement use (i.e., structure and/or function claims), an IND is not required.  Structure and function claims are statements that describe the effect a dietary supplement may have on the structure or function of the human body.  Refer to [FDA Guidance Structure/Function Claims, Small Entity Compliance Guide](https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm103340.htm) for further information.

**5. Can the use of a dietary supplement in a research study qualify for an IND exemption?**

No. The criteria for IND exemption require that the drug product is lawfully marketed as an FDA approved drug in the United States. Unless the dietary supplement used in the research study is also a lawfully marketed FDA approved drug, the IND exemption criteria cannot be considered.

**6. Will an IND be needed if you can buy the dietary supplement at a health food store?**

Yes. If the clinical investigation is intended to evaluate the dietary supplement’s ability to diagnose, cure, mitigate, treat, or prevent a disease, an IND is required, even though you can buy it in a health food store.

**7. Does the health status of the study population matter?**

No. According to FDA Guidance, the clinical condition of study subjects (e.g., the presence or absence of disease) has no bearing on whether the study is subject to the IND requirements. The definition of *clinical investigation* refers only to the fact that subjects are involved in an experiment. It makes no distinction between healthy subjects or those with a disease.

**8. Does it matter if the study information isn’t going to be used for marketing?**

No. Whether the IND regulations apply to a planned clinical investigation does not depend on whether the intent of the clinical investigation is commercial or noncommercial.