Dietary Supplements and INDs

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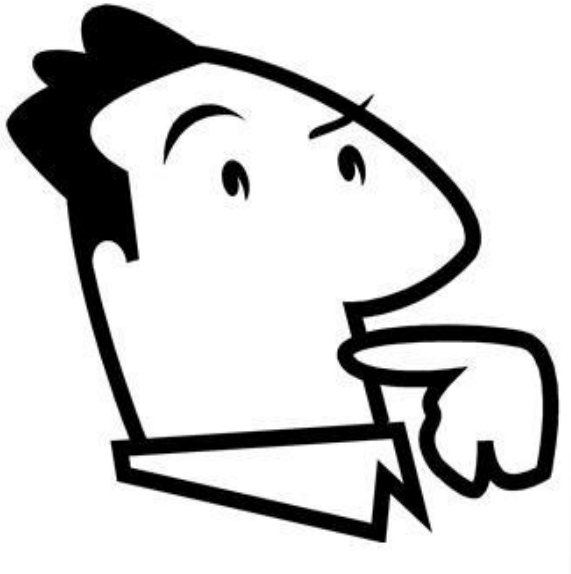
Dietary Supplements and INDs

When does the clinical investigation of a supplement require an IND?

FDA Riddle

When is a dietary supplement not a dietary supplement?



Answer

When it’s a Drug!

Presentation Overview

- FDA Definitions
- Regulation of Dietary Supplements & Drugs
- When dietary supplements become drugs.
- Dietary supplements in approved drug form.
- Tools

DEFINITIONS

FDA Definition of Dietary Supplement

- Product intended to supplement the diet that contains one or more of the following ingredients: vitamin; mineral; herb; botanical; amino acid; dietary substance to supplement the diet by increasing dietary intake; or concentrate, metabolite, constituent, extract or combination of any of the above ingredients.
- Labeled as a dietary supplement; not intended for ingestion as a conventional food or sole item of diet.
- Does not include an item approved as a drug or investigational new drug.

FDA Definition of Food

- Articles used for food or drink for humans or animals and components of those articles.
- Chewing gum.

FDA Definition of Drug

- Articles in US Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, and their supplements.
- Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.
- Articles (other than food) intended to affect the structure or any function of the body of man or other animals.
- Components of the foregoing articles.

Regulation of Drugs & Dietary Supplements

Regulation of Drugs

- To be distributed in interstate commerce, including use in clinical investigations, a drug must be an FDA approved drug or be covered by an IND.
- Major Pathways to Approval:
  - 505(b)(1) New Drug Application
  - Abbreviated Investigational New Drug Application (Generics)
  - 505(b)(2) New Drug Application – for certain changes to approved drugs
  - Over the Counter Monograph System
- Additional "Older" Pathway:
  - GRASE – Generally Recognized as Safe and Effective

Regulation of Dietary Supplements

- **Dietary Supplement Health and Education Act of 1994**
- No FDA pre-market approval of dietary supplements, except in case of new dietary ingredient.
- New dietary ingredient: Manufacturer must provide FDA with evidence it relies on to substantiate safety/effectiveness.
- Manufacturer is responsible for determining that dietary supplements it manufactures or distributes is safe, and claims made are not false or misleading.

When Dietary Supplements become Drugs.

When are Dietary Supplements Treated as Drugs?

- If the dietary supplement is claimed to be for use in the diagnosis, cure, mitigation, treatment or prevention of a disease and its' associated symptoms, then the dietary supplement is considered to be a drug.
- Dietary supplements that claim only that they affect the structure or function of the body of humans or animals are considered dietary supplements.

Do Clinical Investigations of Dietary Supplement Require an IND?

- NO IND REQUIRED IF lawfully marketed dietary supplement is studied for how it affects the structure or function of the body.

- AN IND IS REQUIRED IF the dietary supplement is being studied for whether it cures, treats, mitigates, prevents or diagnoses a disease or associated symptoms.

Clues: Dietary Supplement Types that Need an IND

- When these types of products are used in a clinical investigation, they generally need an IND:
  - Product is part of a class of products intended to treat, diagnose, prevent, mitigate or cure a disease.
  - Product is used as a substitute for a product that treats a disease.
  - Product is used to augment a therapy or drug that is intended to treat, diagnose, prevent, mitigate or cure a disease.
  - Product is a medical food; food for special dietary use; or infant formula.

Clues: Study Purposes that Need an IND

When a clinical investigation has one of the following purposes, it will need an IND:

- Dietary supplement (DS) effects on specific disease or disease class.
- DS effects on signs or symptoms of a disease
- DS effects on condition associated with a natural state or process if the condition is uncommon or can cause serious harm.
- DS role in in body's response to a disease or vector of disease.
- Endpoint that is a disease or symptom of a disease or indication of a disease.

Dietary Supplements in Approved Drug Form

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Dietary Supplements in Approved Drug Form

- Some dietary supplements are also FDA approved drugs, e.g., prescription form of a vitamin.
- If study uses a prescription form of a dietary supplement, then regular IND v. IND exempt criteria apply to the study.
- IND exemption criteria:
  - FDA approved drug
  - No intent to report to FDA as well controlled clinical study in support of new indication or label change, or for prescription drug advertising.
  - No route of administration, dose, patient population or other factor that significantly increases risk or decreases acceptability of risk associated with use of drug.
  - IRB approval
  - Not intended to promote or commercialize the drug.

Bottomline

- If a dietary supplement (includes herbs, botanicals, spices, vitamins or minerals) is used in a clinical investigation that studies its' effects on a disease or disease symptoms, then the dietary supplement will be considered to be a drug.
  - Same rule applies to food, except for medical food or infant formula, which require INDs.
- If the drug used in the study is an "unapproved" drug (i.e., item does not have, or study does not use, an FDA approved prescription or OTC form), then an IND will be required to conduct the clinical investigation.

Tools

IRB Tools

- Decision Tree
- FAQ
- FDA Guidances:
- http://www.fda.gov/downloads/Drugs/Guidances/UCM229175.pdf
- http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm103340.htm

Questions

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