



# National University of Pharmacy

Department of chemistry of natural compound and nutriology



## LECTURE on NUTRICIOLOGY



## DIETARY SUPPLEMENTS



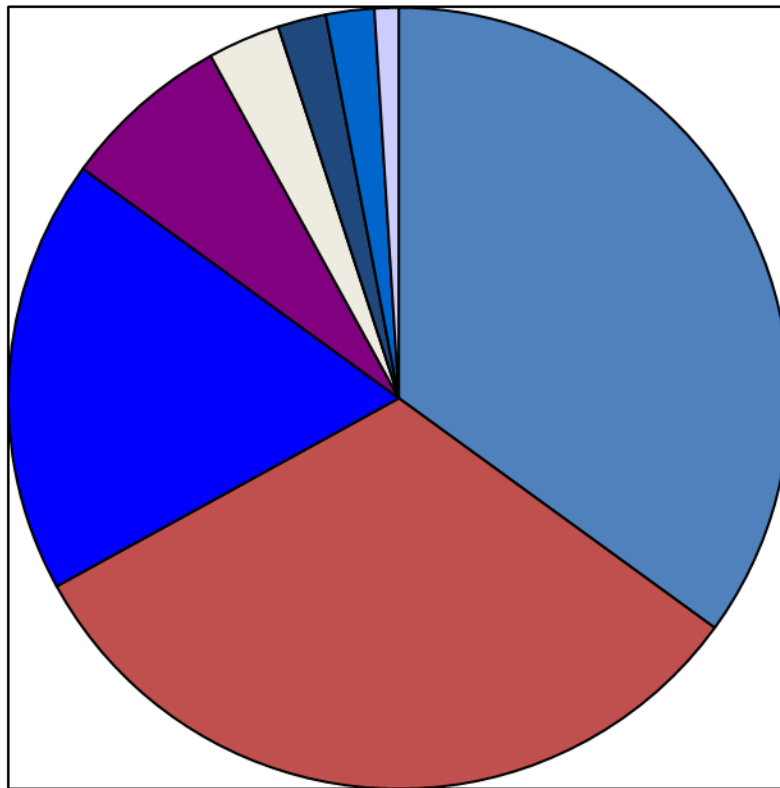
Kharkov 2020



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# World market of dietary supplements



- usa
- europa
- japan
- asia
- canada
- africa
- s.america
- australia

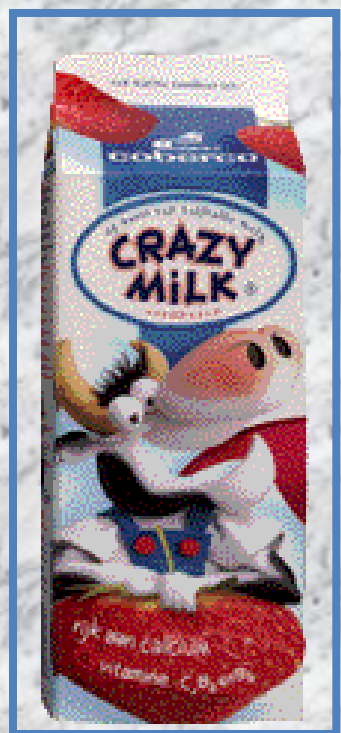
On the world market since 2001, there has been steady growth of dietary supplements (DS) by **7-8% per year.**

In many developed countries of the world production and consumption of dietary supplements reached enormous proportions.

*For example, in Japan DS uses about 90% of the population in the US - 80%, in Europe - more than 65%.*

# Dietary Supplements

*Foods or Drugs?*



## Law of Ukraine “About the safety and quality of food”

- **Dietary Supplements** - vitamin, mineral or vitamin and herbal supplements alone and / or combined in the form of tablets, powders for **oral administration** together with food or added to food within **physiological norms** for further comparison with the conventional power consumption of these substances;
- **Dietary supplements** also include or contain different substances or mixtures of substances, including proteins, carbohydrates, amino acids, edible oils and extracts of plant and animal materials, which are deemed necessary or useful for nutrition and general health;

### **FUNCTIONAL FOODS -**

**food product which comprises as component drugs and / or serves for the prevention or mitigation of disease.**

# Dietary Supplements

- Traditionally defined as products made of one or more essential nutrients such as vitamins, minerals, and proteins, but...
- *DSHEA broadened definition to include almost any product intended for ingestion as a supplement to the diet*
- **Must be identified on label as a D/S**

Dietary Supplement Health and Education Act of 1994 ("DSHEA"), is a 1994 statute of [United States Federal legislation](#) which defines and regulates [dietary supplements](#).<sup>[1]</sup> Under the act, supplements are effectively regulated by the [FDA](#) for Good Manufacturing Practices



# Dietary Supplements

- Distinguished from Drugs:
  - Drug = *article intended to diagnose, cure, mitigate, treat, or prevent disease*
  - Both intended to affect structure and function of body
  - Drug must undergo FDA approval after clinical studies to determine effectiveness and safety
  - *D/S = no pre-market testing*



# Dietary Supplements

- Distinguished from Foods:
  - Foods not *intended* to affect structure and function
  - D/S intended only to *supplement* diet
    - *Not represented for use as conventional food*
    - *Not intended as sole item of a meal or the diet”*

# Dietary Supplements

- *No premarket approval*
- Manufacturer responsible for safety evaluation
- If D/S contains a ***new ingredient***:
  - *Manufacturer must submit information that ingredient “can reasonably be expected to be safe” within 75 days of marketing*
  - ***Safe = no significant risk of illness***

# Labeling of Dietary Supplements

- DSHEA authorized to provide *accurate information* to consumers
- Label must include:
  - *Name of each ingredient*
  - *Quantity of each ingredient*
  - *Total weight of all ingredient if a blend*
  - *Identity of part of plant derived from*
  - *Term “Dietary Supplement”*
- Must contain nutritional labeling information also
  - *Calories, fat, sodium*

# DIETARY SUPPLEMENTS



# Documents about DS

- **USA** – Food and Drug administration regulates this question (*Dietary Supplements Compendium*).
- **Europe** – DS-ingredients are included into *EuPharmacopoeia*.
- **Russia** – certificate of registration; Federal Register; valid for 3 years.
- **Ukraine** – hygienic certificate (now) and development of new edition of *State Pharmacopoeia* with monographs on DS-ingredients.

# Dietary Supplements composition

- **U.S.** - there is an official list of ingredients authorized for inclusion into the DS.
- **Europe** - EU Directive on 10.06.2002: the list of ingredients for the production of DS.
- **Ru** - list of ingredients regulates SanPin 2.3.2.1078-01.
- **Ukraine** - the list is not approved, the RL, which allowed for medical use in the industry of dietary supplements.



- Bilberry = Blueberry = *Vaccinium myrtillus*



Dietary supplement



warella.ucoz.ru



Functional food



Herbal drug





Dietary supplements depending on the effect divided into *three* groups:

PARAPHARMACEUTICALS

NUTRACEUTICAL

PROBIOTICS



## **Nutraceutical can be defined as**

“ A food or part of food or nutrient, that provides health benefits, including the prevention and treatment of a disease.”

- **Nutraceuticals - dietary supplements used to correct the chemical composition of human food (additional nutrient sources):**
- **protein, amino acids, fats, carbohydrates, vitamins, minerals, dietary fiber).**

The **goal** of using nutraceuticals is improvement human nutritional status, health improvement and prevention of a number of diseases.

## **Nutraceuticals, main ingredients :**

- **Vitamins**
- **Vitamin-like substances**
- **Amino acids or peptide complexes**
- **Food fiber**
- **Trace elements**
- **Macronutrients**
- **PUFA**

Nutraceuticals are divided into dosage forms according to their direction of exposure, intended to:

- prevent chronic diseases
- improve health
- delay the aging process
- increase life expectancy
- maintain the structure or function of the body.

# Nutraceuticals



## ДОБАВКИ ДІЄТИЧНІ

Олія із зародків пшениці

Екстракт зародка  
пшеничного харчового  
«Глюкорн»

Шрот зародків  
пшеничних  
харчовий



# PARAPHARMACEUTICALS

- **PARAPHARMACEUTICALS** - dietary food supplements that are recommended to improve the health and prevention of disease, and not for the treatment.
- Word - *PARAPHARMACEUTICALS* means, they are close to medicines ("para" - in Greek - "about").



# CLASSIFICATION of DS

- Depending on the origin of the major components of the DS is divided into:
  - plant extracts, whole plant parts (herbal drugs)
  - bee products,
  - seafood,
  - animal extracts,
  - mineral components,
  - fermentation products,
  - products of biotechnology,
  - synthetic analogues of natural nutrients.

# **PARAPHARMACEUTICALS**

- 1. Controls hunger agent.**
- 2. Natural enzymes-containing agent.**
- 3. Adaptogen.**
- 4. Tonic.**
- 5. Immunomodulators.**
- 6. Hypolipidemental agent.**
- 7. Regulators functions and systems organism.**



1. Dietary supplements that affect on the **central nervous system**
2. DS that affect on **tissue metabolism**
3. DS- sources of **minerals**
4. DS- support **immune** system function
5. DS - sources of **antioxidant** action of substances and substances that affect the **energy** metabolism
6. DS that affect the function of the **cardiovascular** system
7. DS that support function of the **respiratory** system
8. DS that support **digestion** organ function

# Classification of Dietary supplements (DS) based on biological action

- 9. DS for control **body weight**
- 10. DS supporting function of the **genitourinary** system
- 11. DS that support function of the **muscular-skeletal** system
- 12. Ds that affect on humoral factors of **metabolism** regulation
- 13. DS that affect **lactation**
- 14. DS that influence the process of **detoxification** and promotes the excretion of foreign and toxic substances
- 15. Supplements of **various** groups

# Top Ten U.S. Herbal Supplements



- 10.) St. Johns Wort (*Hypericum perforatum*)
- 9.) Ginseng (*Panax ginseng*) 3 species sold in the U.S.
- 8.) Milk Thistle (*Silybum marianum*)
- 7.) Black Cohosh (*Cimicifuga racemosa*)
- 6.) Echinacea (*Echinacea purpurea*)
- 5.) Saw Palmetto (*Serenoa repens*)
- 4.) Ginkgo (*Ginkgo biloba*)
- 3.) Garlic (*Allium sativum*)
- 2.) Cranberry (*Vaccinium macrocarpon*)
- 1.) Soy (*Glycine max*)

- Phytochemicals could provide health benefits as:
  1. Substrate for *biochemical* reactions
  2. *Cofactors* of enzymatic reactions
  3. *Inhibitors* of enzymatic reactions
  4. *Absorbents* that bind to & eliminate undesirable constituent in the intestine
  5. *Scavengers* of reactive or toxic chemicals
  6. Enhance the *absorption* and / or stability of essential nutrients
  7. Selective growth factor for *beneficial bacteria*
  8. *Fermentation substrate* for beneficial bacteria
  9. Selective *inhibitors* of *deleterious* intestinal bacteria

# Various Phytochemicals

Phytochemicals	Source	Role
Tocotrienols & tocopherols	Grains	Suppressed the growth of diverse tumors cell lines via initiation of apoptosis and concomitant arrest of cells in the G1 phase of the cell cycle
Carotenoids	Fruits & vegetables	Antioxidants, protects against uterine, prostate, colorectal, lung and digestive tract cancers, and protection to other antioxidants.

Limonoids	Citrus fruits	Inhibiting phase I enzymes & inducing phase II detoxification enzymes in liver, provide protection to lung tissue.
Phytosterols	Various plants	Exhibit anti-inflammatory, anti-neoplastic, anti-pyretic & immune- modulating activity, decrease cholesterol
Phenolic constituents	Various plants, wholegrain	Antioxidants, lowers the risk of CHD, diabetes, hypertension etc.

Flavonoids	Grapes, wines	Action against free radicals, free radicals mediated cellular signaling, inflammation, allergies, platelet aggregation, & hepatotoxins
Catechin & gallic acids	Grapes, berries, cocoa, green tea, acacia spp.	Antioxidants, free radical scavenging ability, inhibition of eicosanoid synthesis, reduces CHD
Isoflavonoids	Soybeans	Treating cancers & osteoporosis



Anthocyanidins	Fruits & flowers	Antioxidants & anti-mutagenic properties
Glucosinolates	Cruciferous	Activators of liver detoxification enzymes, inhibit the neoplastic effect of various carcinogens
Indoles		Reduces estrogen-dependent cancer risk,
Fiber	Various vegetables, fruits,	Protects against colorectal diseases,

# Dietary supplements **PROBIOTICS**

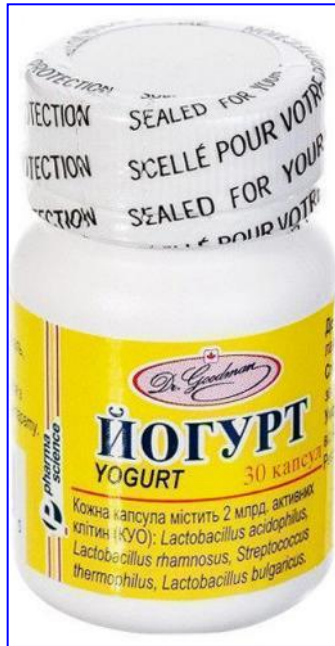
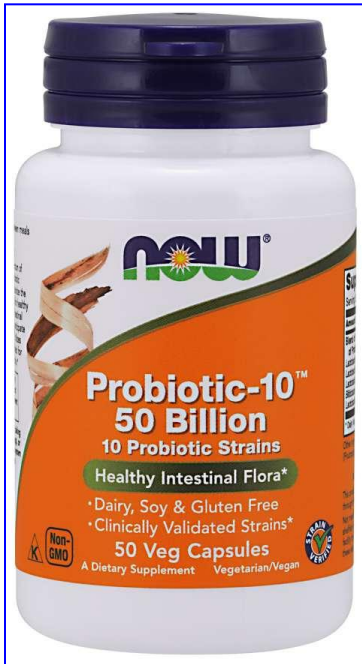
**EUBIOTICS** is a dietary supplement in the form of living microorganisms and (or) substrates and (or) products of their metabolism, which when introduced into the human body have a normalizing effect on the composition and biological activity of the microflora and motility of the digestive tract.

**PROBIOTICS** are living organisms that are used in adequate quantities to restore microbiocenoses.

**PREBIOTICS** are carbohydrates that are not broken down in the upper gastrointestinal tract, as well as other foods that serve as a source of nutrition (substance) for the normal gut microbiota.

**SYNBIOTICS** - therapeutic and prophylactic agents that contain jointly probiotics and prebiotics, ie bifidobacteria and lactobacilli together with the substrate for their reproduction

## PROBIOTICS



## FUNCTIONAL FOOD



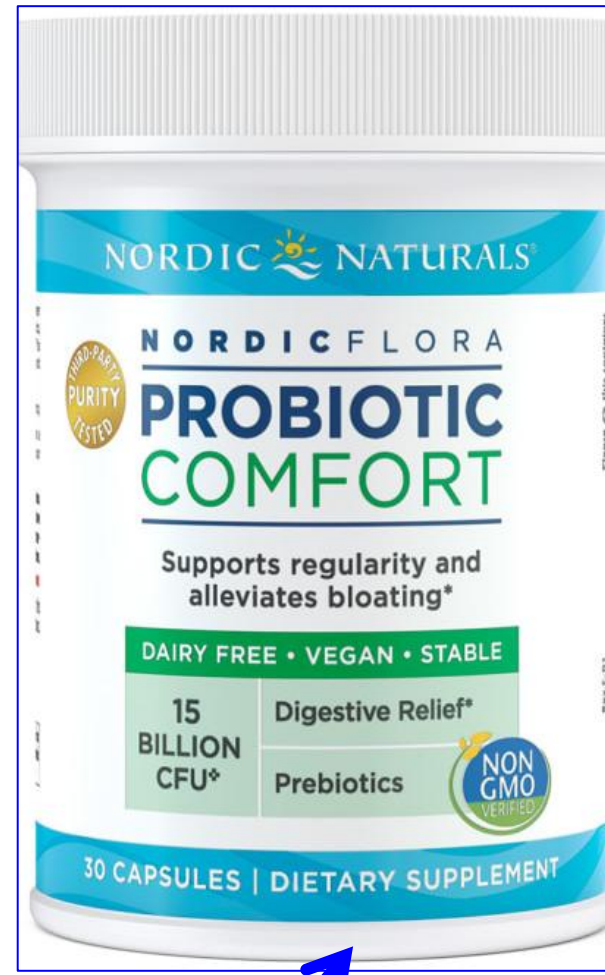
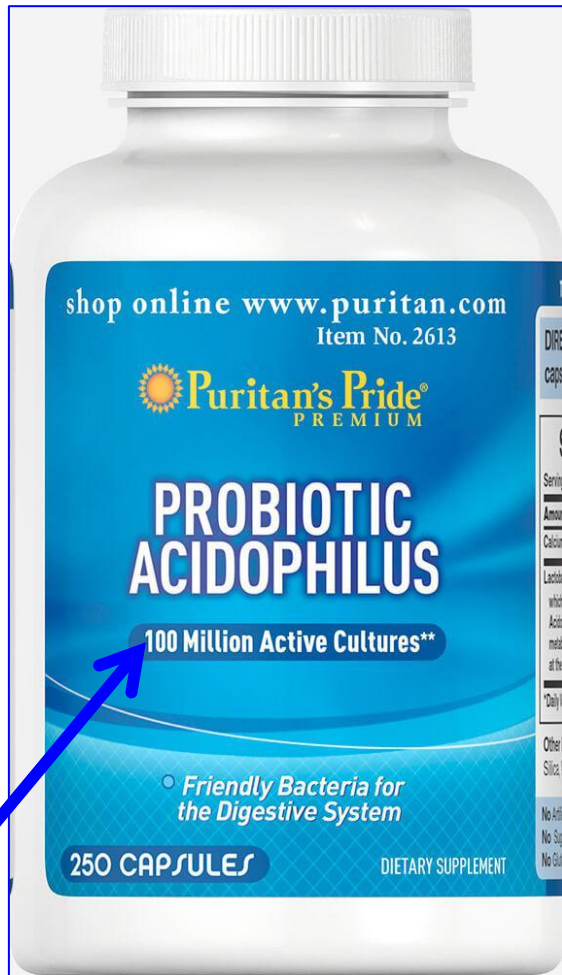
### Факторы, сохраняющие качество кефира ГОСТ 31454– 2012

#### Маркировка

#### Упаковка



# Dietary supplements **PROBIOTICS**



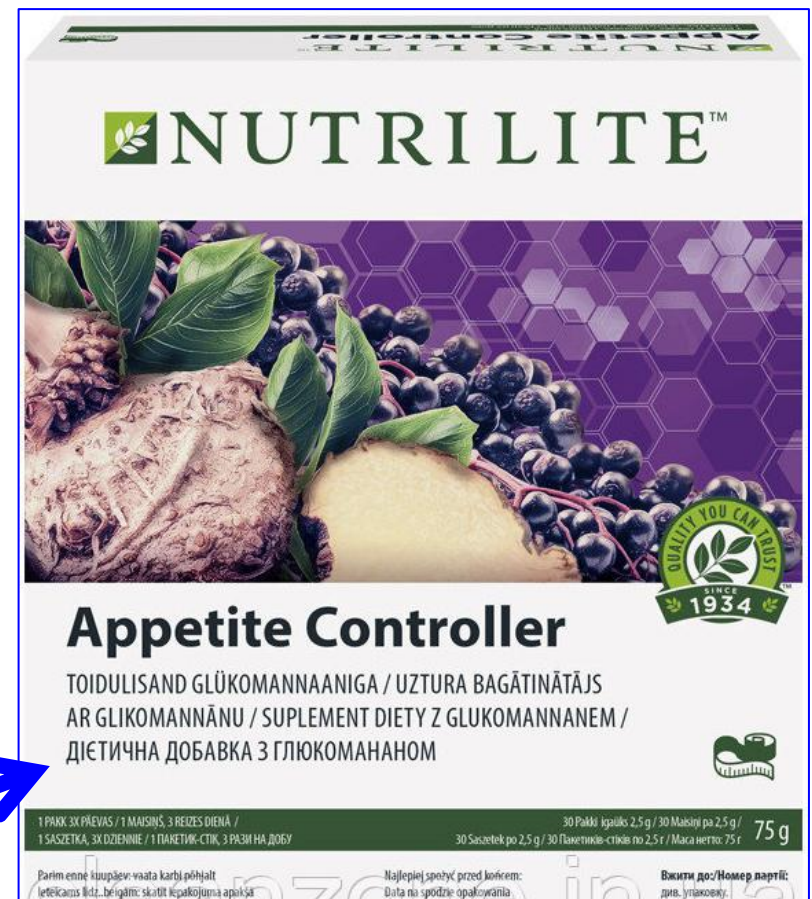


## Dietary supplements label:

- the full name of the product
- normative document
- weight per unit of product packaging
- release form
- expiry date for consumption
- storage conditions
- manufacturer, its address
- lot number
- code

- The product composition
- Food and energy value
- Recommendations for the use or preparation
- Duration of use
- Indications for use
- Contraindications

• **It is not a drug!!  
(Ukraine)**



# Supplements: how are they different from drugs

- Research studies to prove safety are not required
- FDA: cannot take action against manufacture until after product is marketed
- Proven efficacy is not required
- All claims must be followed by statement:
- This statement has not been evaluated by the Food And Drug Administration
- This product is not intended to diagnosis, treat, cure or prevent any disease



# Comparative analysis of drugs and dietary supplements

<i>The comparison criterion</i>	<i>The drug</i>	<i>Food Supplement ( Dietary Supplement )</i>
<b><i>Purpose of the application</i></b>	Prevention, treatment and diagnosis of diseases	Health promotion, disease risk reduction, diet therapy, health food
<b><i>Indications to application</i></b>	Nosological form of the disease	Optimization of metabolism and functional state of individual organs and systems
<b><i>Composition</i></b>	Mono-and multicomponent mixtures of medicines and excipients	Individual nutrients, plant raw materials or multicomponent mixtures
<b><i>Dosage</i></b>	Depends on the pharmacological properties of the substance, the age and condition of the patient	Acceptable daily intake dose approved by chief state sanitary doctor (in Ukraine)
<b><i>Mode of application</i></b>	Oral, sublingual, parenteral, etc.	Only orally with food
<b><i>Product form</i></b>	Various medicinal forms	Granules, tablets, powders, liquids for internal use in conjunction with food

# Comparative analysis of drugs and dietary supplements

<i>Effective-ness</i>	Determined on the basis of pharmacological studies	Determined on the basis of information about action of the ingredients or permission for application of a particular supplement
<i>Safety</i>	Determined by carrying out of the complex of toxicological and medical-biologic researches	Approved label; dependence "dose-response" has not been experimentally established
<i>Side effects</i>	Specifically listed	Of a general nature
<i>Bioavailability</i>	Clinical studies	Not established
<i>Quality control</i>	According to normative documents	Sanitary-Epidemiological Conclusion (in Ukraine)
<i>Registration authority (in Ukraine)</i>	State Pharmacological Center of the Health Ministry of Ukraine	State Sanitary and Epidemiological Service of Ukraine

Supportive but not conclusive research shows that consumption of EPA and DHA Omega-3 fatty acids may reduce the risk of coronary heart disease. (See nutrition information for total fat, saturated fat and cholesterol content).

**No Color Added • No Artificial Flavors • No Preservatives • No Yeast or Starch • Gluten Free**

**SUGGESTED USE:** Take 2 softgels daily with a meal. For easier swallowing, take with water before and during ingestion.

## Supplement Facts

Serving Size 2 Softgels  
Servings Per Container 50

Amount Per Serving	% DV
Calories 35	
Calories from Fat 25	
Total Fat 3 g	5%**
Saturated Fat 1 g	5%**
Polysaturated Fat 1 g	
Monounsaturated Fat 0.5 g	
Cholesterol 25 mg	8%**
Total Carbohydrates 1 g	less than 1%**
Protein Less than 1 g	
Fish Oil Concentrate 2400 mg	*
Total Omega-3 Fatty Acids 720 mg	*
Omega-3 EPA (Eicosapentaenoic Acid) 360 mg	
Omega-3 DHA (Docosahexaenoic Acid) 240 mg	
Omega-3 Other 120 mg	

\*Daily Value (DV) not established.

\*\*Percent Daily Values are based on a 2,000 calorie diet.

† This statement has not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure or prevent any disease.

Keep bottle tightly closed. Store in a cool, dry place, out of reach of children.

**Do not use if imprinted seal under cap is broken or missing.**

**Caution:** If you are pregnant or nursing, or taking medication, facing surgery, have bleeding problems, or undergoing any other treatment which may affect the ability of blood to clot, consult your physician before taking this product.

**OTHER INGREDIENTS:** Gelatin, Glycerin, Water, Tocopherols.

**CONTAINS:** Fish (Anchovy, Sardine, Mackerel).

**Distributed by:**

**Nature Made Nutritional Products,**  
Mission Hills, CA 91346-9606, U.S.A.  
**1-800-276-2878**

**www.NatureMade.com**

Fish Oil Country of Origin is Peru.

Encapsulated and quality tested in the U.S.A.

USP has tested and verified ingredients,

potency and manufacturing process.

USP sets official standards for dietary

supplements. [www.uspverified.org](http://www.uspverified.org)

† Based on Pharmacy Times Survey of

pharmacists recommending Omega-3/

Fish Oil Supplements.

# How to Read the Label

# Dietary Supplement Label

Supplement Facts	
Serving Size 2 Softgels	
Servings Per Container 50	
Amount Per Serving	% DV
Calories 35	
Calories from Fat 25	
Total Fat 3 g	5%**
Saturated Fat 1 g	5%**
Polyunsaturated Fat 1 g	
Monounsaturated Fat 0.5 g	
Cholesterol 25 mg	8%**
Total Carbohydrates 1 g	less than 1%**
Protein Less than 1 g	
Fish Oil Concentrate 2400 mg	*
Total Omega-3 Fatty Acids 720 mg	*
Omega-3 EPA (Eicosapentaenoic Acid) 360 mg	
Omega-3 DHA (Docosahexaenoic Acid) 240 mg	
Omega-3 Other 120 mg	
*Daily Value (DV) not established.	
**Percent Daily Values are based on a 2,000 calorie diet.	

**Serving Size:**

**How many tablets or capsules you should take**

**%DV:**

**Indicates the amount that the serving size represents**

# Dietary Supplement Label



## **Lot Number:**

- **Series of letters and numbers that help track a product**

## **Expiration Date:**

- **How long the ingredients will be effective**

# Dietary Supplement Label

Supplement Facts	
Serving Size 2 Softgels Servings Per Container 50	
Amount Per Serving	% DV
Calories 35	
Calories from Fat 25	
Total Fat 3 g	5%**
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Do not use if imprinted seal under cap is broken or missing.

Caution: If you are pregnant or nursing, or taking medication, facing surgery, have bleeding problems, or undergoing any other treatment which may affect the ability of blood to clot, consult your physician before taking this product.

OTHER INGREDIENTS: Gelatin, Glycerin, Water, Tocopherols.

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USP sets official standards for dietary supplements. [www.uspverified.org](http://www.uspverified.org)  
† Based on Pharmacy Times Survey of pharmacists recommending Omega-3/ Fish Oil Supplements.

## Ingredients:

- Vitamin or mineral ingredients in each tablet or capsule
- List of potential allergens, fillers, binders, flavorings also included

## Manufacturer Contact Information:

- Address and telephone number should be provided
- Contact with questions or concerns

# Tips for Using Dietary Supplements Safely

- Always talk with your pharmacist and doctor before starting or stopping a dietary supplement
- This is especially important when:
  - A supplement contains an ingredient that is used for the same reason as another medicine you are taking
  - A supplement contains multiple ingredients
  - You are combining dietary supplements with prescription or over-the-counter (OTC) medicines



# **COMMON INTERACTIONS WITH DIETARY SUPPLEMENTS**

# Medicines that Interact with Dietary Supplements

- Birth Control Pills/Morning After Pill
  - Some dietary supplements may speed up how quickly birth control pills are removed from the body
  - This increases the chance of pregnancy
  - **St. John's wort**
    - St. John's wort supplements that contain the ingredient hyperforin interfere with birth control pills
    - Do not combine birth control pills with St. John's wort

# Medicines that Interact with Dietary Supplements

- **Warfarin** (Coumadin®)
  - The INR is a test that measures how quickly your blood clots
  - The INR is used to help determine the dose of warfarin
  - Many medicines interact and can increase or decrease your INR test
  - **Coenzyme Q10, Cranberry, Vitamins E & K, Garlic (raw garlic and garlic extracts, Fish Oil)**

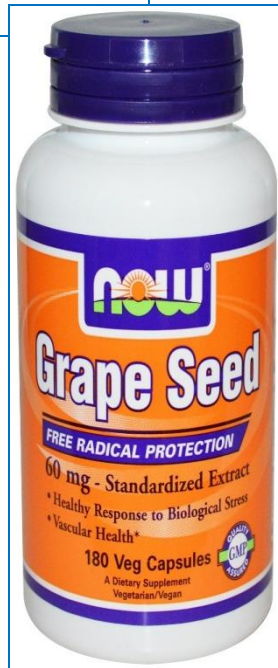
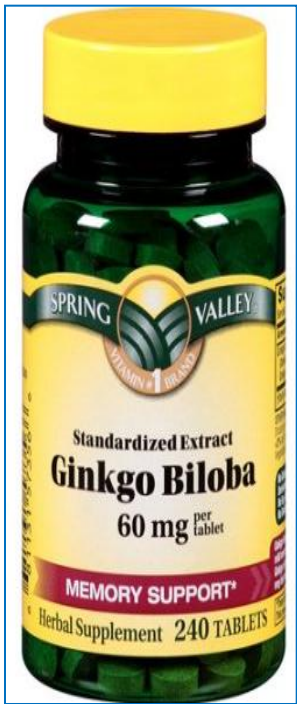
# Medicines that Interact with Dietary Supplements

- Some dietary supplements may block how platelets work
- Ineffective platelets can't stop bleeding once it begins
  - Vitamin E (800 Units or more per day)
  - Vitamin K
  - Garlic (raw garlic and garlic extracts)
  - Very high doses of fish oil (although evidence of this interaction is not that strong)

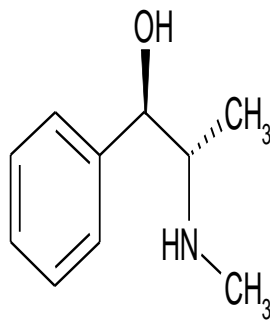
# How To Choose...

- Look for **standardized** supplements (USP)
- Buy only **single-name** supplements
- Beware of claims that sound **too good to be true**
- Be extremely cautious about supplements **manufactured outside of USA**
  - Europe is an exception

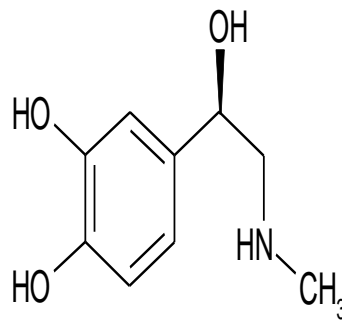




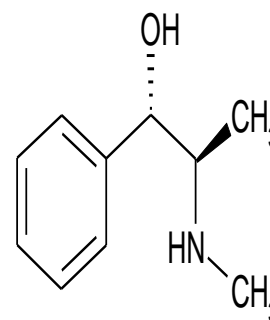
# Ma huang



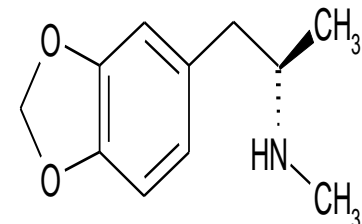
*(-) ephedrine*



*adrenaline*



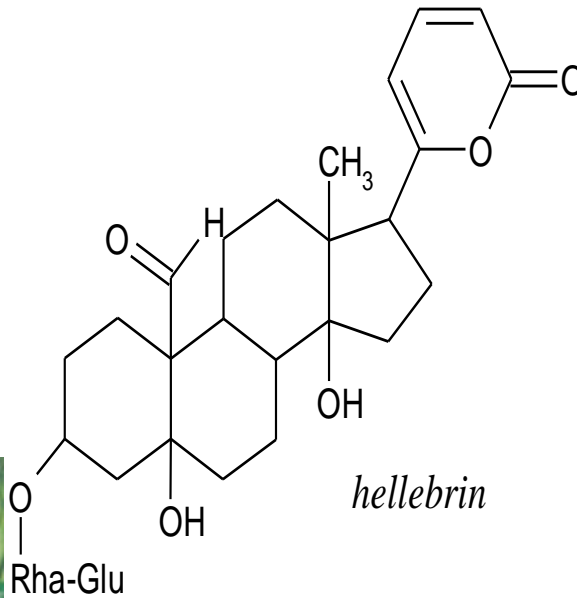
*(+)- pseudoephedrine*



*MDMA (ectasy)*



# Helleborus caucasicus, Ranunculaceae



# All in all

DS is not drug (but may be look like drug),  
divided into: parapharmaceuticals, nutraceutical  
and probiotics

DS should have special label which resemble as  
drug as food

DS can't contain toxic, hallucinogenic or other  
type of dangerous ingredients

DS may interact with drugs, consult your  
doctor or pharmacist

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