



**COLEGIADOS...UNIDOS
SOMOS MÁS FUERTES**

DON'T BE CONFUSED WITH NUTRITIONAL SUPPLEMENTS: USE AND EXPECTATIONS OF THESE SUPPLEMENTS



Disclosure to Learners

Carmen M Nevárez Alonso, faculty for this CE activity, has no relevant financial relationship(s) with ineligible companies to disclose.

“THE COLEGIO DE
FARMACÉUTICOS DE PUERTO RICO
IS ACCREDITED BY THE
ACCREDITATION COUNCIL FOR
PHARMACY EDUCATION AS
A PROVIDER OF CONTINUING
PHARMACY EDUCATION.”

PROVIDER NUMBER: 0151





Objetivos

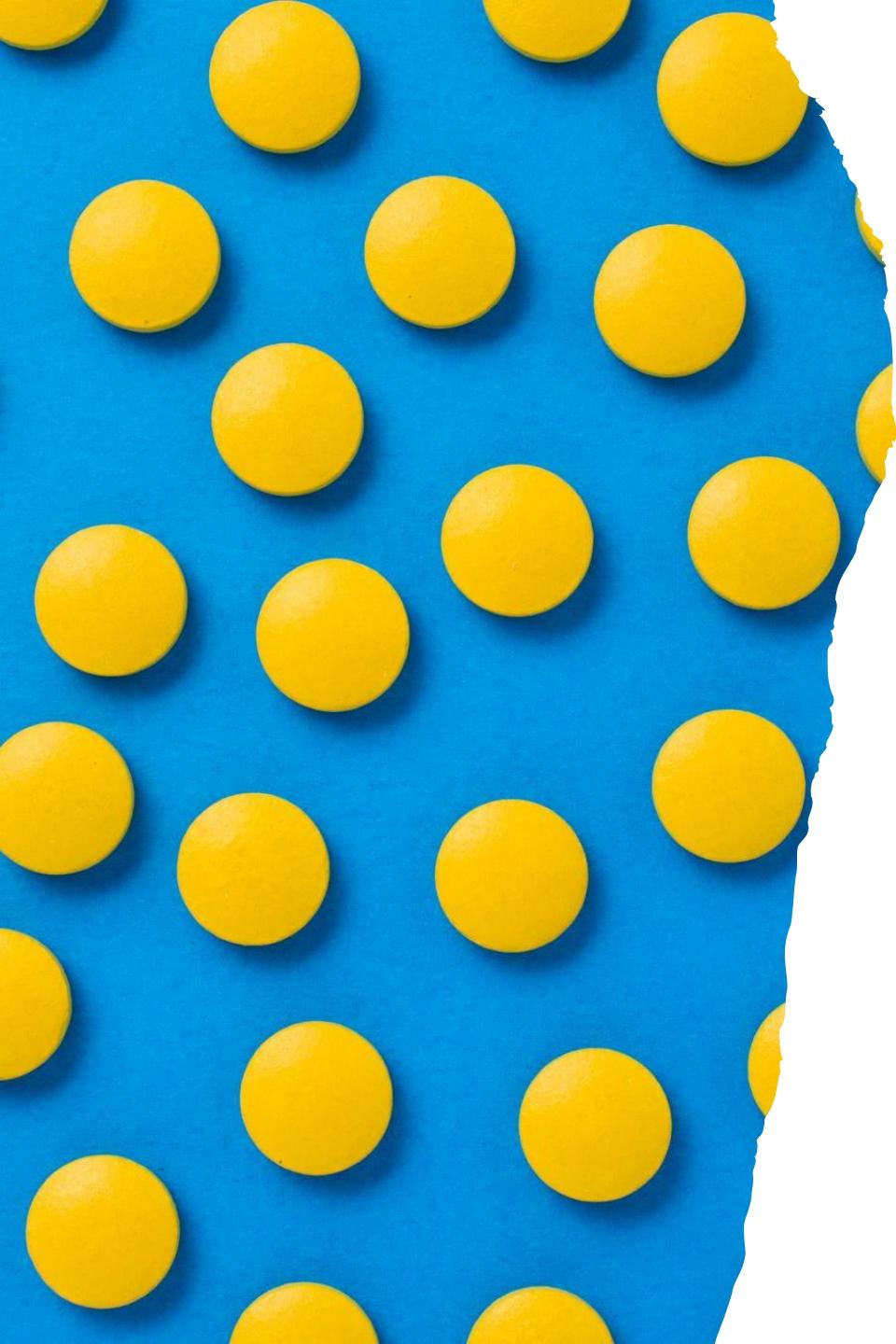
Objetivos

Define what a nutritional supplement is.

Describe the difference between drug and a nutritional supplement.

Describe how nutritional supplements are regulated, manufactured and marketed.

Identify known interactions between nutritional supplements and medications.



Contenido

Definiciones: :

- Suplemento nutricional
- Natural
- Sustancia química
- Drogas

Industria de los Suplementos Nutricionales: ¿cuán grande y poderosa es?

Acta: “Government’s standards for nutritional supplement manufacture. (DSHEA Act) de 1994

Interacción entre suplementos nutricionales y medicamentos

Describir algunos suplementos mercadeados para:

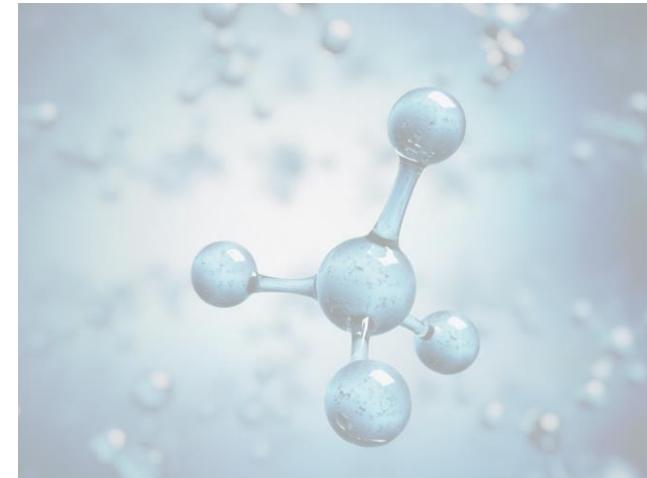
- Manejo de peso
- Artritis
- Inflamación
- Diabetes Mellitus
- Incremento de masa muscular
- Memoria



Table 3 Percent of subjects citing various reasons for using dietary supplements, in NHANES 2007–2011 and in two CRN surveys, one in 2011 on consumer use of dietary supplements and one in 2009 on use by dietitians

Reason for use	NHANES 2007–2010 [3]	CRN Consumer survey, 2011 [5]	CRN survey, dietitians, 2009 [11]
Overall health:			
Improve overall health	45%		
Maintain health	33%		
Overall health/wellness		58%	53%
Bone health	25%	30%	58%
Supplement the diet, fill nutrient gaps	22%	42%	42%
Prevent health problems	20%	26%	
Heart health, lower cholesterol	15%	29%, 19%	25%, 16%
Boost immunity, prevent colds	15%	32%, 17%	25%, 21%
Healthy joints, prevent arthritis	12%	20%	15%
Enhanced energy	11%	31%	15%
Skin, hair and nails	5% (skin only)	17%	13%
Bowel or colon health, digestive health	5%	15%	26%
Eye health	4%	13%	9%
Mental health or focus, concentration	4%	13%	
Weight loss, weight management	3%	14%	6%

(Includes questions asked in at least two of the three surveys; response rounded to nearest percent).



¿Qué es una sustancia química?

¿Qué es una sustancia natural?

¿ Puede una sustancia natural ser una sustancia química?

¿Las sustancias químicas existen en la naturaleza?

Las sustancias naturales: ¿se pueden replicar en un laboratorio?

¿QUÉ ES UNA SUSTANCIA NATURAL?

- Compuesto químico o sustancia producida por un organismo vivo, - que se puede encontrar en la naturaleza. (1)
- Cualquier sustancia producida por la naturaleza. (1)
- Productos naturales pueden también ser preparados a través síntesis química (total o parcial) (1)

FDA: "natural" to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food.(2)

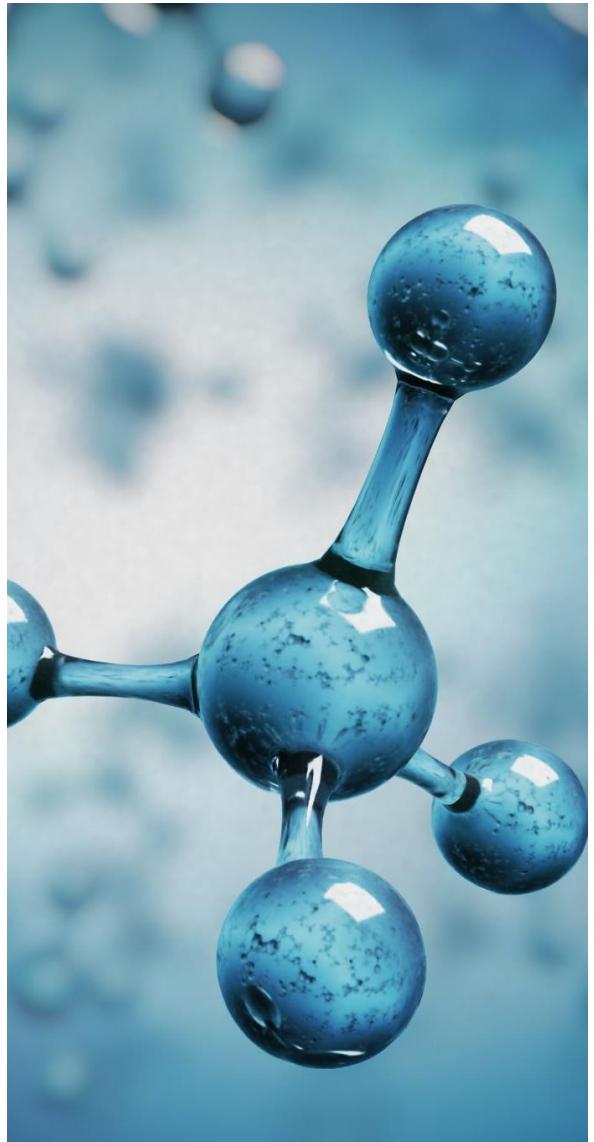
USDA: A product containing no artificial ingredient or added color and is only minimally processed. Minimal processing means that the product was processed in a manner that does not fundamentally alter the product. The label must include a statement explaining the meaning of the term natural (such as "no artificial ingredients; minimally processed").(2,3)

1 All natural. *Nat Chem Biol* **3**, 351 (2007). <https://doi.org/10.1038/nchembio0707-351>

2 <https://www.fda.gov/food/food-labeling-nutrition/use-term-natural-food-labeling>

3 <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms#:~:text=NATURAL%3A,not%20fundamentally%20alter%20the%20product>

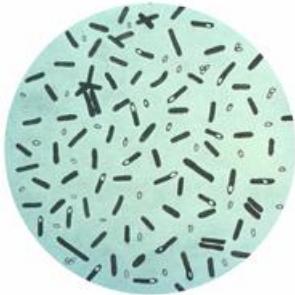
4 https://redarrowusa.com/wp-content/uploads/USDA_Natural_Definition_Statement.pdf



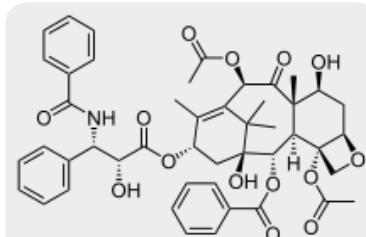
Sustancia química

- A chemical substance may well be defined as "any material with a definite chemical composition"

- Hill, J. W.;2005



Botulinum toxin (tipos A Y B) (Botox, Dysport, Xeomin, MyoBloc), utilizados en la medicina y cosmetología son productos naturales que provienen de la bacteria Clostridium botulinum



Paclitaxel(Taxol) Producto natural derivado del árbol yew.
Quimioterapia(*Taxus brevifolia*, Pacific yew o western yew)



Penicilina, antibiótico, derivado del hongo *Penicillium chrysogenum*



Droga analgésica ω -conotoxin (ziconotide) producto natural derivado de l caracol de mar *Conus magus*

Richard Parker - Conus magus 56mm Uploaded by JoJan Conus magus 56mm



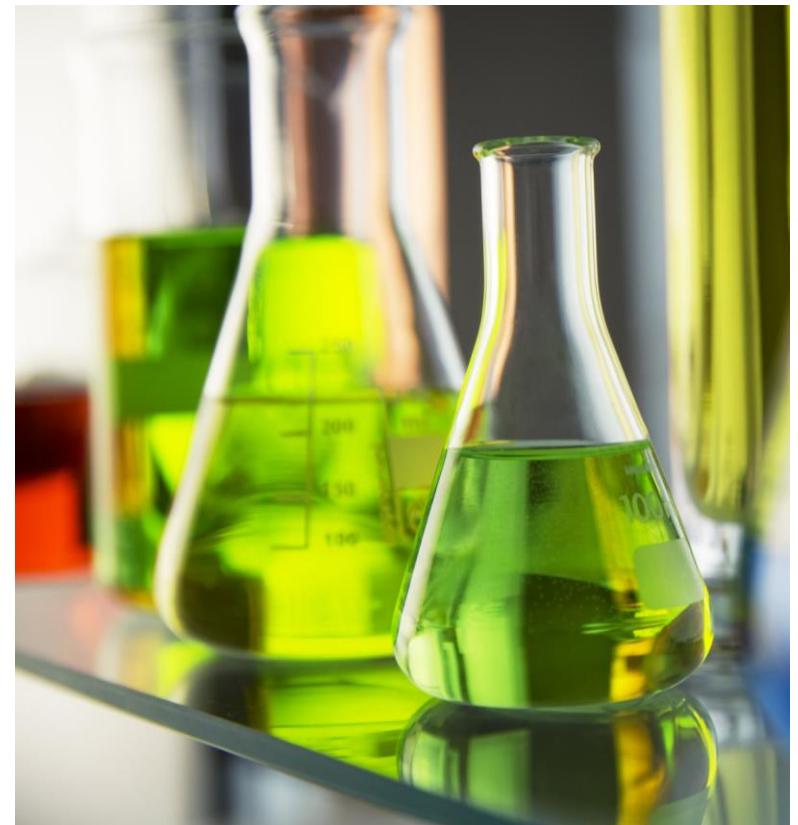
Salicin (alcoholic β -glucoside)
convertido en ácido salicílico
por el cuerpo (aspirina)
(white willow bark, yellow willow bark)



Morfina, droga, opioide analgésico derivado de la planta *Papaver somniferum*

¿Cuál de los siguientes son sustancias/compuestos químicos?

- Leucina
- Clorox
- Líquido de fregar
- Composta
- Glucosamina
- Glucosa



D R O G A

.....“intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals ...”;

.....a second definition is “articles (other than food) intended to affect the structure or any function of the body of man or other animals ...”;

.....and a third definition states that a product is a drug if it is “**recognized in the official U.S. Pharmacopeia (USP), official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them**” (FDCA, P.L. 75-717, 52 Stat. 1040 [1938], as amended 21 U.S.C. § 321(g) [2001]).

A drug is defined as: A substance recognized by an official pharmacopoeia or formulary. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. A substance (other than food) intended to affect the structure or any function of the body.

Institute of Medicine (US) and National Research Council (US) Committee on the Framework for Evaluating the Safety of Dietary Supplements. Dietary Supplements: A Framework for Evaluating Safety. Washington (DC): National Academies Press (US); 2005. 1, Introduction and Background. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK216048/>

<https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#:~:text=A%20drug%20is%20defined%20as,any%20function%20of%20the%20body.>

Active ingredient is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals.

The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Active moiety (fracción activa): is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

Nutraceuticos (nutraceutical)

Stephen L. DeFelice: (1989) A nutraceutical has elsewhere been defined as 'a functional food that aids in the prevention and treatment of disease(s) and or disorders (except anemia)' (1)

The European Nutraceutical Association: 'nutritional products which have effects that are relevant to health ... which are not synthetic substances or chemical compounds formulated for specific indications ... contain[ing] nutrients (partly in concentrated form) (1)

Nutraceuticals must not only supplement the diet but should also aid in the prevention and/or treatment of disease and/or disorder. (2)

Health Canada: a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food, demonstrated to have a physiological benefit or provide protection against chronic disease (1)

1Aronson JK. (2017)

2 Kalra EK. (2003)

¿Suplemento Nutricional?



“Agencias reguladoras”

Estados Unidos

FDA: Federal Drug Administration

FTC: Federal Trade Commission

Asoc. Americana de Productos
Herbarios

Europa

European Commision Health & Food Safety

Comisión de Expertos para el Uso de
Fitofarmacéuticos

Comisión E (1978-1993)

Un poco de historia

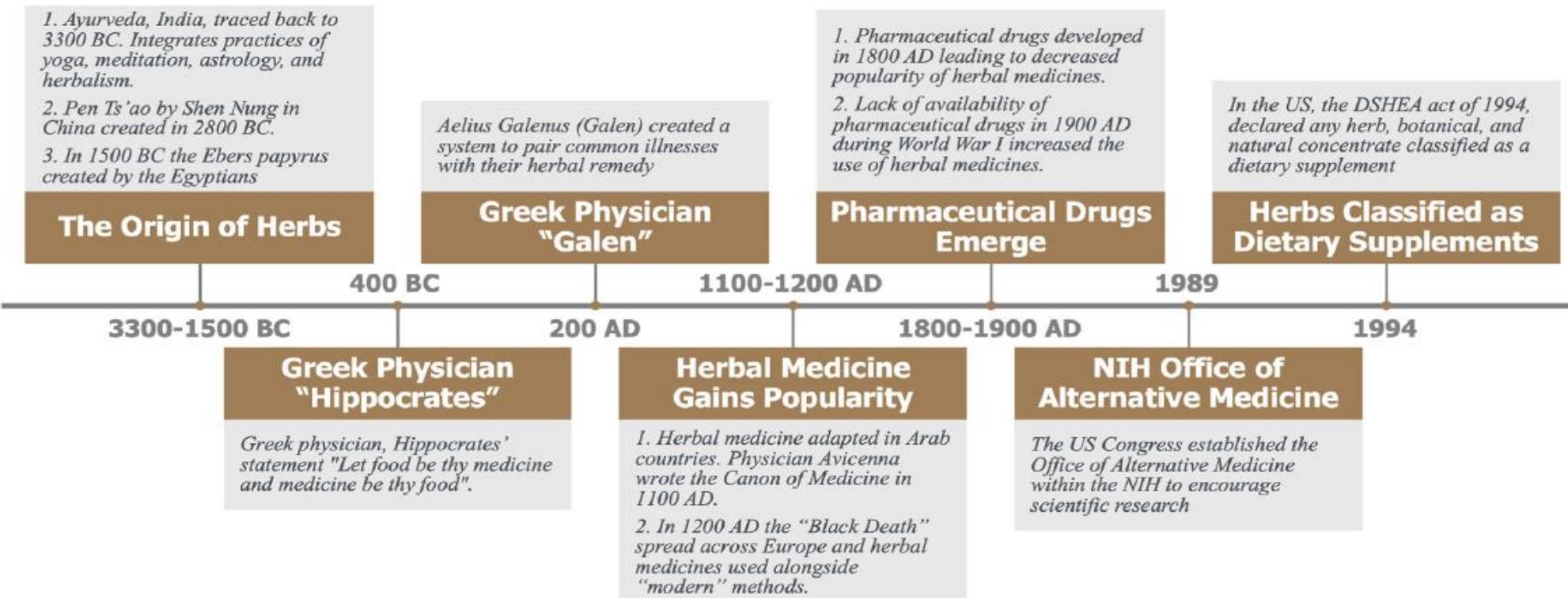


Fig. 1. A historical timeline linking dietary supplements to the origin of herbal medicine.

UN POCO DE HISTORIA

- Ceguera nocturna: Egipcios, Babilonios, Griegos (1800BC) (1)
- Escorbuto (2)
- Linus Carl Pauling (3)
- 1994: Dietary Supplement Health and Education Act of 1994.(4,5)

1 Al Binali HA. 2014

2 <https://health.mil/News/Articles/2022/01/10/The-British-Limeys-Were-Right-A-Short-History-of-Scurvy?page=2#youMayAlso>

3 Hemilä H. 1997

4 Institute of Medicine (US) and National Research Council (US) Committee 2005

5 NIH: Dietary Supplement Health and Education Act of 1994.

Suplementos Nutricionales

Legal Definition of a Dietary Supplement as Defined by the Dietary Supplement Health and Education Act of 1994

The term dietary supplement:

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

Dietary supplements are further defined as products that are labeled as dietary supplements and are not represented for use as a conventional food or as a sole item of a meal or the diet. Supplements can be marketed for ingestion in a variety of dosage forms including capsule, powder, softgel, gelcap, tablet, liquid, or, indeed, any other form so long as they are not represented as conventional foods or as sole items of a meal or of the diet (FDCA, as amended, § 402).

Dos tipos de ingredientes:
Ingredientes dietarios
Substacias como: preservativos, endulzadores, rellenos, excipients...

Dietary Supplement Health and Education Act of 1994

- 1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;
- (2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;...**
- (3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and**
- (B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;
- (4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

Dietary Supplement Health and Education Act of 1994

(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements; ...

Dietary Supplement Health and Education Act of 1994

- 9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;
- (10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;
- 11) the United States will spend over \$1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;
- (12)(A) the nutritional supplement industry is an integral part of the economy of the United States;
- (B) the industry consistently projects a positive trade balance; and ...**

Dietary Supplement Health and Education Act of 1994

- (C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least \$4,000,000,000;
- (13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers

14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and ...

(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and ...

(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

Anatomia de la etiqueta

¿Qué debe incluir la etiqueta?

- Declaración de identidad (nombre del producto): la etiqueta debe decir “suplemento alimenticio” o “suplemento” precedido por el tipo de ingrediente(s) en el producto, como “suplemento de fibra”.
 - Cantidad neta de contenido
 - Lista de ingredientes, que indica todos los ingredientes del producto, incluidos los aditivos.
 - Fabricante, empacador, nombre y dirección del distribuidor: debe incluir el nombre corporativo y la dirección de la entidad (a menos que la dirección figure localmente).
 - Número de teléfono o dirección postal nacional de los EE. UU. a la que un consumidor puede informar un evento adverso grave.
 - Tabla de datos complementarios
- These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Office of Nutritional Products, Labeling and Dietary Supplements, ONPLDS. Center for Food Safety and Applied Nutrition, CFSAN)

Enmiendas al Acta DSHEA de 1994

- Cualquier suplemento que tenga vitaminas, minerales, hierbas, amino ácidos debe tener el “**Supplement Fact**”
- Servicio apropiado
- Cantidades específicas de los componentes cuando tengan RDI
- Mencionar las vitaminas/minerales para los que no se tiene RDI
- Describir el contenido de “Dietary Blends”

Office of Nutritional Products, Labeling and Dietary Supplements, ONPLDS. Center for Food Safety and Applied Nutrition, (CFSAN)

Enmiendas al Acta DSHEA de 1994

- “**High Potency**”:
 - Una sola vitamina o mineral: cuando se tiene el 100% del RDI
 - Multiples ingredientes: Cuando se tiene el 100% del RDI para 2/3 partes de los componentes
- **Antioxidante:** uso permitido solo si el ingrediente ha demostrado capacidad de inhibir radicales libres o evita reacciones químicas iniciadas por los radicales

Office of Nutritional Products, Labeling and Dietary Supplements, ONPLDS. Center for Food Safety and Applied Nutrition, (CFSAN)

Nuevo ingrediente

- Un nuevo ingrediente dietético es un ingrediente dietético que no fue comercializado en los Estados Unidos antes del 15 de octubre de 1994 y no incluye ningún ingrediente dietético que fue comercializado en los Estados Unidos antes del 15 de octubre de 1994.
- 21 U.S.C. 350b(c)

Afirmaciones (claims) en la etiqueta

Pueden estar presentes

- Terminos asociados a cantidad aprobados por Dep. de Agricultura Federal
- Reclamos de salud
- Reclamos cualificados de salud
- ✓ Reclamos sobre tejidos y funciones
- ✓ Bien estar general
- ✓ Reclamos sobre deficiencias nutricionales

NO aprobadas

- Reclamos implicitos o explicitos, a menos que haya una explicación fundamentada.
- Reclamos NO sustentados, que afectan estructuras y tejidos

Afirmaciones aprobadas usando términos de cantidad aprobados por el Departamento de Agricultura Federal (USDA)

- §101.54(b) Afirmaciones de *High* (alto)
- §101.54(c) Afirmaciones de *Good Source* (buena fuente)
- §101.54(e) Afirmaciones de *More* (más)
- §101.54(f) Afirmaciones de *High potency* (alta potencia)
- §101.54(g) Afirmaciones de *Antioxidant* (antioxidante)
- §101.56 Afirmaciones de *Light* o *Lite* (liviano)
- §101.60 Afirmaciones de *Calorie* or *Sugar* (caloría o azúcar)
- §101.61 Afirmaciones de *Sodium* or *Salt* (sodio o sal)
- §101.62 Afirmaciones de *Fat, fatty acids, and cholesterol* (grasas, ácidos grasos y colesterol)
- §101.65 Afirmaciones implícitas de contenido de nutrientes.
- §101.65(d) Afirmaciones de *Healthy* (saludable)
- §101.67 Uso de las afirmaciones de contenido de nutrientes para mantequilla.

Reclamos de salud: “Health Claims”

Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition.

Diets low in fat “may” or “might” reduce the risk of some cancers...

Diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber “may” or “might” reduce the risk of heart disease...

Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

<https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard>

Reclamos cualificados de salud: Qualified health claims (QHCs)

Qualified health claims (QHCs) are supported by scientific evidence, but do not meet the more rigorous “significant scientific agreement” standard required for an authorized health claim.

To ensure that these claims are not misleading, they must be accompanied by a disclaimer or other qualifying language to accurately communicate to consumers the level of scientific evidence supporting the claim

Supportive but inconclusive scientific evidence suggests that consuming at least 200 mg of cocoa flavanols daily, such as provided by high flavanol cocoa powder, or high flavanol semisweet or high flavanol dark chocolate, may reduce the risk of cardiovascular disease. This product contains at least 200 mg cocoa flavanols per serving. See nutrition information for _____ and other nutrients.” (1/febrero/ 2023)

Very limited and preliminary evidence suggests that calcium supplements may reduce the risk of colon/rectal polyps. FDA concludes that there is little scientific evidence to support this claim.“(12/octubre/2005)

[fda.gov/food/food-labeling-nutrition/qualified-health-claims#:~:text=Qualified%20health%20claims%20\(QHCs\)%20are,for%20an%20authorized%20health%20claim.](https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims)

Reclamos sobre tejidos y funciones/Structure and function claims

Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example,

Calcium builds strong bones.

Fiber maintain normal bowel regularity

Reclamos sobre bienestar general/General well being claims

General well-being claims describe general well-being from consumption of a nutrient or dietary ingredient.

[xxxx] support the proper functioning of a healthy immune system

<https://www.fda.gov/food/food-labeling-nutrition/structurefunction-claims>

Webinar/National Association of Boards of Pharmacy, 2021

Afirmaciones de deficiencias nutricionales/Nutritional deficiency claims

Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease but such claims are allowed only if they also say how widespread such a disease is in the United States.

Scurvy is a disease that mostly occurs in pirates of the 1700.....X% of the population is expected to suffer from scurvy.

Puede un suplemento:

¿Estar mal etiquetado (misbranding)?

Adulterado

Ingrediente no cumple con definición de suplemento nutricional.

Es mercadeado con los reclamos de curar/ diagnosticar/tratar una enfermedad.

Contiene ingredientes venenosos o que puedan causar daño a tejidos.

Contiene un ingrediente nuevo que no haya sido notificado a la FDA.

Compañía no ha mostrado evidencia contundente de que el nuevo ingrediente es seguro.



Agencia federal encargada de evaluar todo tipo de propaganda.

Verifica que los anuncios sean:

- Claros
- Informativos
- Información/reclamos esté fuertemente sustentada con evidencia segura y clara

Example 4

An ad for a dietary supplement called “Arthricure” claims that the product maintains joint health and mobility into old age. The “before” picture shows an elderly women using a walker. The “after” picture shows her dancing with her husband. The images and product name likely convey implied claims that the product is effective in the treatment of the symptoms of arthritis, and may also imply that the product can cure or mitigate the disease. The advertiser must be able to substantiate these implied claims.

Example 5

An advertisement for a multi-vitamin/mineral supplement claims that the product can eliminate a specific mineral deficiency that results in feelings of fatigue. In fact, less than 2% of the general population to which the ad is targeted suffers from this deficiency. The advertiser should disclose this fact so that consumers will understand that only the small percentage of people who suffer from the actual mineral deficiency are likely to experience any reduction in fatigue from using the product.



Example 6

An advertiser for a weight loss supplement cites a placebo-controlled, double-blind clinical study as demonstrating that the product resulted in an average weight loss of fifteen pounds over an eight-week period.

The weight loss for the test group is, in fact, significantly greater than for the control subjects.

However, both the control and test subjects engaged in regular exercise and followed a restricted-calorie diet as part of the study regimen. The advertisement should make clear that users of the supplement must follow the same diet and exercise regimen to achieve the claimed weight loss results.

Debemos tener en mente que.....

- “Natural” does not always mean “safe.”
- Manufacturer’s use of the term “standardized” (or “verified” or “certified”) does not necessarily guarantee product quality or consistency
- Be aware that an herbal supplement may contain dozens of compounds and that all of its ingredients may not be known..
- Also consider the possibility that what’s on the label may not be what’s in the bottle. Analyses of dietary supplements sometimes find differences between labeled and actual ingredients. For example:
- An herbal supplement may not contain the correct plant species.
- The amounts of the ingredients may be lower or higher than the label states.
- The dietary supplement may be contaminated with other herbs, pesticides, or metals, or even adulterated with unlabeled, illegal ingredients such as prescription drugs.



IMPORTANTE

FDA no tiene la autoridad de aprobar un suplemento nutriconal (por seguridad o eficacia) o su etiquetado antes de que salgan al mercado

La introducción de ingredientes nuevos ocurre, sin notificación a la FDA

<https://www.fda.gov/media/158288/download>; Dietary Supplements: what pharmacist should know

Prevalencia

Consumo de suplementos nutricionales ha tenido un incremento consistente en la ultima década.

Es un comportamiento global

RESEARCH

Open Access



A cross-sectional study of self-reported dietary supplement use, associated factors, and adverse events among young adults in Kuwait

Dana AlTarrah^{1*}, Zahraa ElSamra², Wahibe Daher^{2,3}, Alanood AlKhas² and Lolwah Alzafri⁴

• 2019 Dec;44(6):1135-1140.

Prevalence of Dietary Supplement Use and Associated Factors Among College Students in the United Arab Emirates

Radwan H., 2019

AlTarrah et al. 2024

RESEARCH ARTICLE

Prevalence, attitudes, and practices of dietary supplements among middle-aged and older adults in Asir region, Saudi Arabia: A cross-sectional study

Amani Alhazmi^{1*}, Beena Brigit Kuriakose², Sakeena Mushfiq¹,
Khursheed Muzammil¹, Manal Mohammed Hawash^{1,3}

Alhazmi A, et al 2023

Los suplementos consumidos con mayor frecuencia son: multivitaminas, Vit C, y Vit D

FlorisWardenaar et al (2016). Self-Reported Use and Reasons among the General Population for Using Sports Nutrition Products and Dietary Supplements. Sports 2016, 4, 33; doi:10.3390/sports4020033



El patrón de consumo de suplementos:

- Se ha mantenido estable desde 1999-2012
 - Uso de MTV ha disminuído
- Tendencia a aumento de suplementos específicos (VitD, Ω-3)

Kandor et al (2016). Trends in Dietary Supplement Use Among US Adults From 1999-2012. JAMA. 11;316(14):1464-1474. doi: 10.1001/jama.2016.14403

Table 1 Prevalence of dietary supplements use in men and women, by age group, NHANES 2003–2006 [1]

	Men	Women
Age 19-30	36%	43%
Age 31-50	44%	55%
Age 51-70	58%	72%
Age >70	66%	75%

Dickinson A, et al 2014.

- Características del consumidor
- 2/3 partes de la población de los Estados Unidos de America consume algún tipo de suplemento nutricional

En promedio:

Buscan desarrollar estilos de vida más saludables

Mayor grado de educación

Mayor ingreso economico por unidad familiar

Más prevalente en mujeres que en varones

Mayor tendencia a tener mejores habitos de alimentación (usan suplementos para mejorar deficiencias)

Evitan el tabaco

Mantenimeinto de un mejor peso corporal

Realizan ejercicio regularmente



75% de los atletas reportaron haber utilizado algún suplemento en los pasados 12 meses (no diferencias entre sexo)

Atletismo: 91.7%

Gimnasia 100%

Halterofilia 83.3%

Karate 88.9%

Judo 75%

H. Heredia. (2009) Utilización de Suplementos Dietarios en Atletas Nacionales de Deportes de Fortaleza-Potencia y de Combate Afiliados al Comité Olímpico de Puerto Rico .

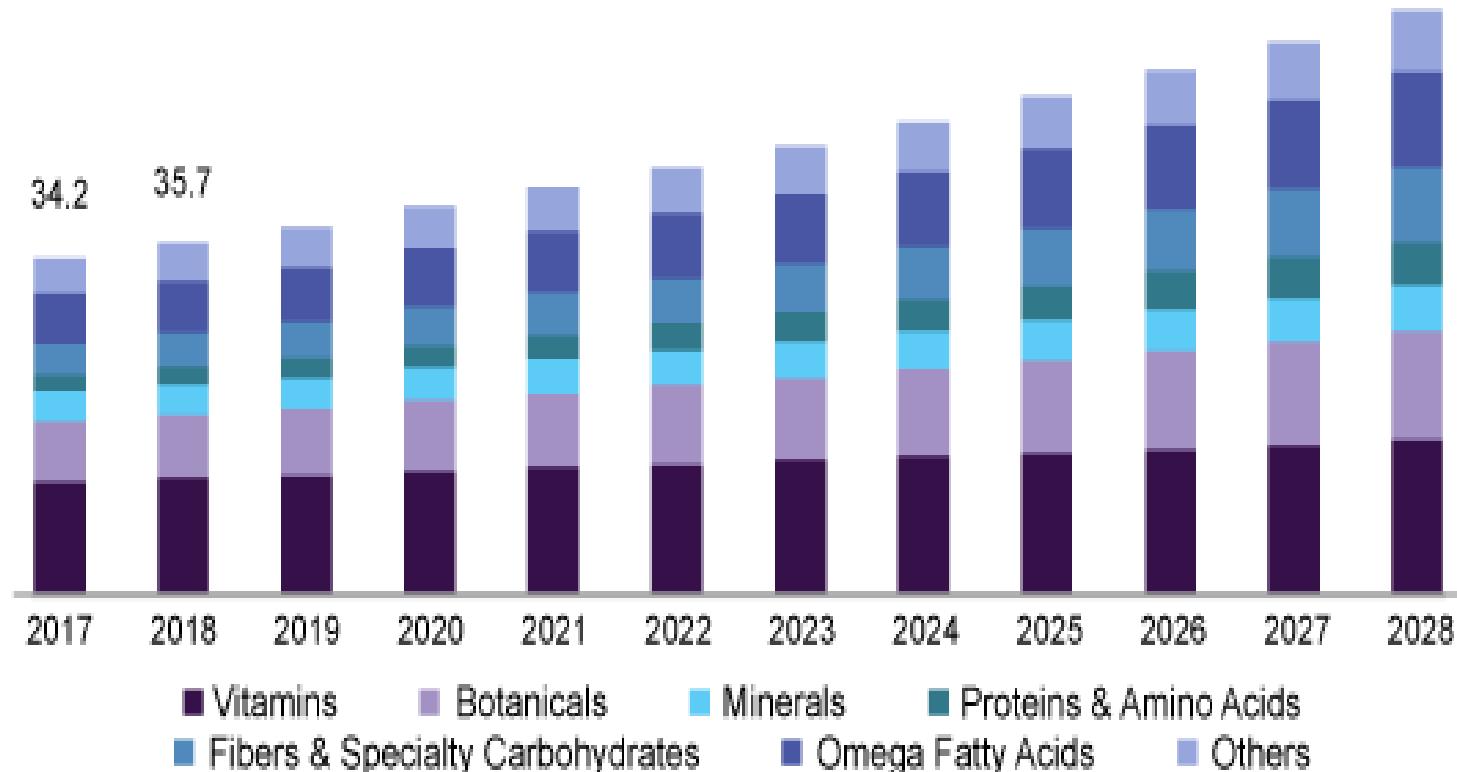
LA INDUSTRIA DE LOS SUPLEMENTOS NUTRICIONALES

¿Cuál es su poderío?

Market Overview and Key Trends

The global dietary supplements market has witnessed rapid growth in recent years and is expected to grow at a CAGR of 9.5% between 2023 and 2030. The market was valued at USD 162154.5 million in 2022 and is expected to reach USD 335152.1 million in 2030. Data Source:-
<https://www.credenceresearch.com/report/dietary-supplements-market>

U.S. dietary supplements market size, by ingredient, 2017 - 2028 (USD Billion)



Source: www.grandviewresearch.com

Dietary Supplements Market Size, Share & Trends Analysis Report By Ingredient (Vitamins, Proteins & Amino Acids), By Form, By Application, By End User, By Distribution Channel, And Segment Forecasts, 2021 - 2028

Incursión compañías farmaceuticas en el negocio de los suplementos nutricionales

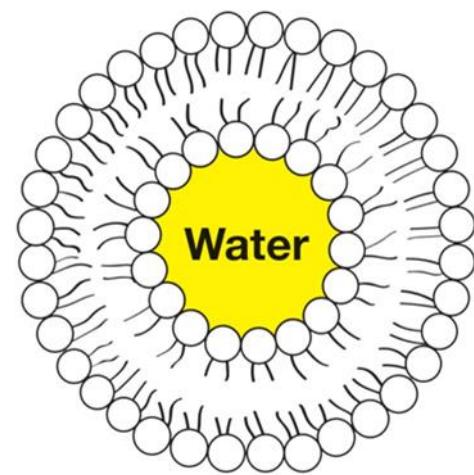
- Vencimiento patentes
- Cabildeo en el Senado para crear legislación difícil de cumplir por compañías pequeñas
- Compra de compañías grandes con ofertas muy tentadoras
 - **Bayer**: compra de Schift Nutrition International por 1.2 billones (2012)
 - **Pfizer**: compra Alacer (Emergen-C) por 360 millones (feb 2012)
 - **Procter&Gambler**: compra New Chapter por 250 millones (marzo 2012)

Stokowski-Bisanitni Jeanine. Pharmaceutical Bayer acquires nutritional supplement company Schift. Examiner.com. Rescatado agosto 6, 2013

Tableta
Polvo
Softgels
Suero intravenoso
Tecnología Liposomal



Presentaciones



Producción y manufactura

Caseras : muy poco control de calidad, cantidad, inocuidad.

Grandes compañías que diseñan los productos según deseo del cliente .



[How To Start Your Own Supplement Company | Quality Supplement MFG](#)

qualitysupplementmfg.com

How many businesses are there in the Vitamin & Supplement Manufacturing industry in the US in 2023?

There are 1,439 Vitamin & Supplement Manufacturing businesses in the US as of 2023, an increase of 4% from 2022.

The number of businesses in the Vitamin & Supplement Manufacturing industry in the US has grown 4.0% per year on average over the five years between 2018 - 2023.

Which States have the highest number of businesses in the Vitamin & Supplement Manufacturing industry in the United States?

California (288 businesses), New Jersey (142 businesses) and New York (122 businesses) are the States with the most number of Vitamin & Supplement Manufacturing businesses in the US.



Cada año, cerca de 23,000 visitas a sala de emergencia y 2,000 hospitalizaciones son atribuidas al uso de suplementos dietarios

Seguridad

Credibilidad

Entre enero del 2009 y diciembre de 2012 la FDA retiró del mercado 279 suplementos.

66.7% de estos suplementos que podían ser comprados a través de internet, contenían las sustancias **NO seguras** para consumo humano... Continuaban en el mercado aún 6 meses después del llamado hecho por la FDA.

Cohen e al. (2014). Presence of Banned Drugs in Dietary Supplements Following FDA Recalls PreJAMA. 2014;312(16):1691-1693. doi:10.1001/jama.2014.10308

El contenido de colecalciferol de los suplementos “OTC” y compuestos de vitamina es altamente variable, con una potencia que fluctuó entre 9-146%solo la mitad de las pildoras de Vit D y 1/3 de los suplementos compuestos completaban los requisitos de USP Convention Standards. Los suplementos que eran verificados por USP, mostraron menor variación..

LeBlanc et al. (2013) Over-the-Counter and Compounded Vitamin D: Is Potency What We Expect? JAMA INTERN MED VOL 173 (NO. 7), APR 8, 2013

- 634 suplementos (proteína, amino ácidos,, creatina, carnitina, ribosa, guarana,piruvato, Bhidroxi - Bmetilbutirato, Tribulus Terristris....)
 - 251 suplidores, 13 países diferentes
 - Rotulación no indicaba utilización de ingredientes precursores de hormonas
 - 94 tenían hormonas o precursores
 - 68% precursores de testosterona
 - 7% precursores de nandrolona
 - 25% precursores de ambos
 - 49 tenían un estroide
 - 45 más de un esteroide
- Países productores
EEUU
Alemania
Reino Unido

Geyger et al, 2004, Analysis of non-hormonal nutritional supplements for anabolic-androgenics steroids, results from an international study. Int J S med

- GNC; Herbal Plus
 - Target: "Up & Up"
 - Walgreens: “Finest Nutrition”
 - Walmart: “Spring Valley”



- Gingko Biloba
 - St. John's Wort
 - Ginseng
 - Garlic
 - Echninacea
 - Saw Palmetto

“a **ginseng** pill from Walgreens marketed for increased endurance and vitality — but contained little more than **garlic and rice** powder.

Another was a ginkgo biloba supplement from Walmart that was mainly a mix of powdered **radish**, **houseplants**, and **wheat** — and **its label said it was wheat- and gluten-free.**”



ANSWER

ISSN 1062-1024 • 10

—
—
—

1.2. *Initial flow from a well*

III. STATE A RECAP ORGANIZATION

卷之三

This latter constitutes a demand to reduce anti-discriminatory legislation to the ratio of established conflicts established by local citizens' organisations, and in particular to immediately stop the ratio of five "Burkini Blasphemous" convictions in identified local communities (the additional seven local families).

We advised that the statutory framework is authority by Executive Law § 6(3)(c) to investigate allegations and processes involving which persons based upon conduct or engage in threatening to their business operations. Executive Law § 6(3)(c) authorizes that after a reasonable period of time, such investigations into business activities and later advertising, the state has the power to prosecute for "any crime or property offense" for which a defendant has failed certain public "tests and requirements," and also caused that it can take major proceedings across the country to prosecute individuals and entities.

BMPEA.....'Super Caffeine'

- On April 23, 2015, the FDA issued warning letters to five companies regarding a total of eight products for which the product labeling lists BMPEA as a dietary ingredient. Two of the companies further identified the source of this stimulant as the botanical **Acacia rigidula**

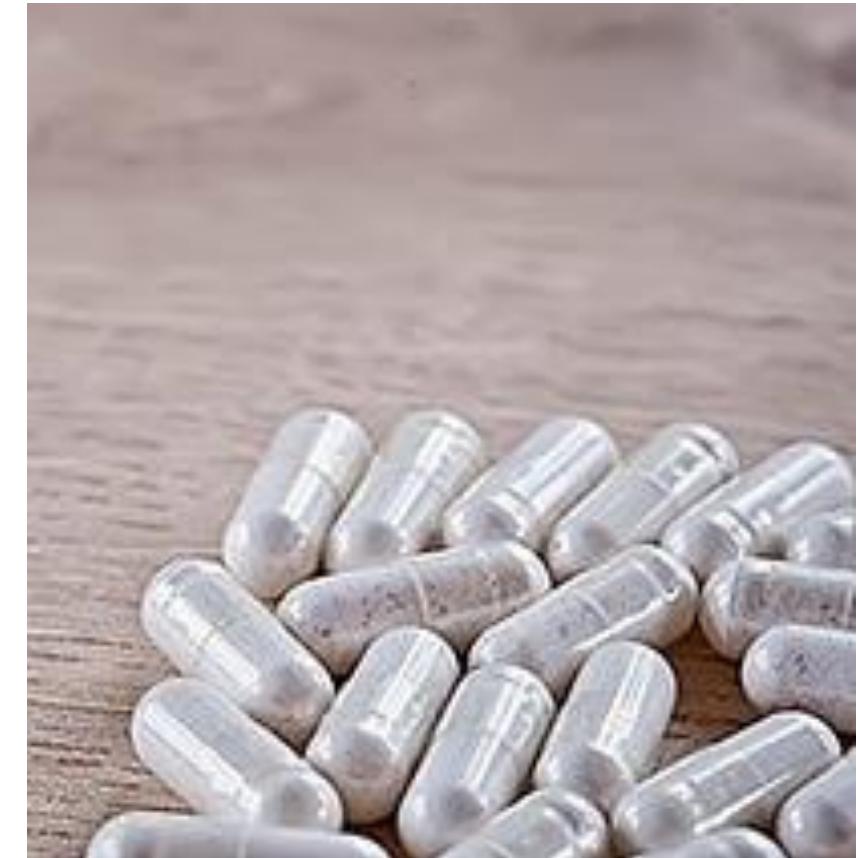
- βMePEA
- R-beta-methylphenethylamine
- R-beta-methylphenethylamine HCl
- Beta-methylphenethylamine
- β-methylphenylethylamine
- 1-amino-2-phenylpropane
- 2-phenylpropan-1-amine
- 2-phenylpropylamine
- alpha-benzylethylamine
- 1-phenyl-1-methyl-2-aminoethane
- beta-methylbenzeneethanamine
- beta-phenylpropylamine
- 2- phenyl-1-propanamine

- **Hi-Tech Pharmaceuticals, Inc.** (Products: Fastin-XR - extended release), Fastin-RR (rapid release), Lipodrene (Ephedra Free)
- **Tribavus Enterprises, LLC d/b/a iForce Nutrition** (Products: Conquer (Fruit Punch Slam & Raspberry Lemonade flavors)
- **Train Naked Labs LLC** (Products: Critical FX, Sudden Impact)
- **Better Body Sports, LLC** (Product: Phoenix Extreme)
- **Human Evolution Supplements, Inc.** (Product: Core Burner)

<https://www.cdc.gov/>

- Epi investigation finds steroid-laced vitamins and minerals; Purity First offers product recalls
-
- ***What was the problem?***
- In March 2013, the New York State Department of Health (NYSDOH) began investigating an unusual cluster of symptoms among persons taking dietary supplements from a single manufacturer, Purity First. Reported health effects varied, ranging from unusual hair growth in women, to fatigue, muscle pain, and anxiety. Some patients had elevated liver enzymes and cholesterol levels.
- The NYSDOH laboratories tested several supplements produced by Purity First, which revealed that there were anabolic steroids present in some of the products, specifically the vitamin B-50 and multi-mineral supplements.

<https://www.cdc.gov/>





NABP

National Association of
Boards of Pharmacy

Enforcement

- **FDA**
Warning letters, investigations, arrests
- **DOJ**
Complaints (often in conjunction with FDA)
- **State Attorneys General**
Oregon led the charge against major retailers that sold dietary supplements containing picamilon and BMPEA



The banner features the Oregon Department of Justice seal at the top left, followed by the word "Media" in large serif letters. The background shows a blurred image of the Oregon State Capitol building with flags flying in front.

Oregon Files Lawsuit Against GNC for Selling Nutritional Supplements with Ingredients Not Approved in U.S.

October 22, 2015 • Posted in [Media Release](#)

Attorney General Ellen Rosenblum today filed a lawsuit against General Nutrition Corporation, GNC, for selling nutritional and dietary supplements containing the illegal ingredients picamilon and BMPEA. The lawsuit alleges that the company violated the Oregon Unlawful Trade Practices Act (UTPA) by misrepresenting certain products as lawful dietary supplements when they are actually unapproved drugs that may not be lawfully sold in the United States as a dietary supplement. The complaint also alleges that GNC sold products labeled as containing botanical acacia rigidula that had been spiked with unlabeled BMPEA.

"It is scary to know that certain products sold by GNC contain an ingredient that is not even labeled—let alone approved in the United States," said Attorney General Rosenblum. "When Oregonians buy a dietary supplement, they deserve to know that the ingredients in the products are safe and comply with the law. There are 25 GNC stores in Oregon that sold thousands of these products over the span of a couple of years."

The lawsuit, which was filed in Multnomah Circuit Court, also alleges that GNC sold thousands of units of products in Oregon that contained picamilon or BMPEA that were falsely labeled as a dietary supplement.

Picamilon is a synthetic chemical that is not approved in the United States, but is used as a prescription drug in some countries to treat neurological conditions. Products containing BMPEA, a powerful stimulant and amphetamine-like substance, are sometimes sold as weight loss or performance enhancing nutritional supplements.

POR FRAUDE

Mellado se querella ante los federales

MARGA PARÉS ARROYO
marga.pares@gfrmedia.com

La promoción de un suplemento natural que asegura tener propiedades que supuestamente ayudan a controlar la presión arterial y balancear los niveles de glucosa en sangre, entre otros beneficios a la salud, figura como uno de los más recurrentes esquemas de fraude.

Así lo anunció el secretario de Salud, el doctor Carlos Mellado, quien radicó ayer una querella en el Negociado Federal de Investigaciones (FBI, por sus siglas en inglés) por este particular.

"Tengo conocimiento de pacientes que están gastando sobre \$300 porque están utilizando figuras de médicos reconocidos como el doctor Fernando Cabanillas, el doctor Iván González Cancel y la mía, que no puedo promocionar nada, (para promocionarlo)", denunció Mellado.

Según el galeno, se trata de un producto llamado "Blood Balance", el cual se ha estado anunciando por las redes sociales y gestionando sus ventas a través del correo.

"Ya en el FBI están investigando. Esto es un fraude (particularmente) con pa-

cientes mayores. Sé de, al menos, cuatro pacientes mayores que han gastado sobre \$300 en este producto", comentó.

La querella que radicó en el FBI, sostuvo, es por usar falsamente su imagen en la promoción del producto.

MÚLTIPLES ENGAÑOS

Mientras, Cabanillas indicó que sabe de al menos seis productos que han utilizado falsamente su imagen para su promoción, incluyendo este.

"Con inteligencia artificial me ponen a hablar, promoviendo productos como ese, Blood Balance, que jamás había ni oido", dijo el oncólogo.

Agregó que hay pacientes que incluso llaman a su oficina médica reclamando que no les ha enviado el producto que compraron.

"El FBI tiene una querella hace por lo menos tres meses y no han hecho nada", indicó el galeno.

Limary Cruz Rubio, portavoz de prensa del FBI, comentó, por su parte, que no podía ni confirmar ni negar que se estaba investigando este asunto.



"Ya en el FBI están investigando. Esto es un fraude (particularmente) con pacientes mayores", dijo el secretario de Salud Carlos Mellado.

Archivo

<https://telemundopr.app.link/XUBR1bMVwLb>

Interacción suplemento- medicamento

Clientes pueden experimentar reacciones adversas:

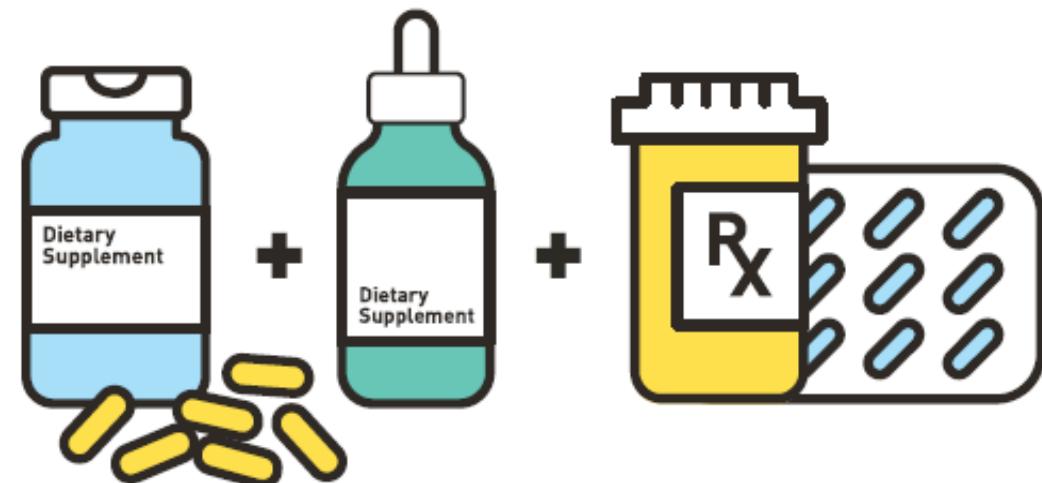
Suplementos + medicamentos recetados

Suplementos + OTC

Combinación de suplementos

Combinación de suplementos en altas dosis

Poli-suplementos/poli-farmacia



Interacción suplementos nutricionales y medicamentos

Interacción mecanismos farmacocinéticos – farmacodinámicos

Alteración o modificación de la barrera gastrointestinal:

Enzima: CYP3A4

- Absorción
- Distribución
- Transportadores
- Inducción enzimas metabólicas
- Eliminación renal de drogas-metabolitos

Interacción directa con plasma sanguíneo

- Distribución
- Transportadores
- Inducción enzimas metabólicas
- Eliminación renal de drogas-metabolitos
- Toxicidad

Suryanarayana Polaka, et al (2022).

Web results

[Handbook of Drug-Nutrient Interactions | Joseph I. Boullata ...](#)

[www.springer.com](#) › book

Handbook of Drug-Nutrient Interactions, Second Edition is an essential new work that provides a scientific look behind many drug-nutrient interactions, ...

[Handbook of Drug-Nutrient Interactions | SpringerLink](#)

[link.springer.com](#) › book

Handbook of Drug-Nutrient Interactions, Second Edition is a comprehensive up-to-date text for the total management of patients on **drug** and/or nutrition therapy but also an insight into the recent developments in **drug-nutrition interactions** which will act as a reliable reference for clinicians and students for many ...

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[edisciplinas.usp.br](#) › mod_resource › content › Handbook...

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[Nutrition - drug-nutrient interactions - Pharmaceutical Journal](#)

[www.pharmaceutical-journal.com](#) › download

PDF

knowledge of **drug-nutrient interactions**. This allows them to ... components. Nutrient absorption Drugs can affect ... Pharmaceutical Nutrition Group **handbook**.9

Furanocoumarin

- aliskiren (Tekturna) – (jugo de manzana y china)
- alprazolam (Xanax)
- amiodarone (Pacerone)
- atogepant (Quilpta)
- atorvastatin (Lipitor)
- budesonide (Entocort EC, Ortikos, Tarpeyo, Uceris)
- buspirone (Buspar)
- Zocor (simvastatin)
- Procardia and Adalat CC (both nifedipine).
- Neoral and Sandimmune capsule or oral solution (both cyclosporine).
- BuSpar (buspirone)
- Allegra (fexofenadine).

<https://www.fda.gov/consumers/consumer-updates/grapefruit-juice-and-some-drugs-dont-mix>

<https://www.drugs.com/article/grapefruit-drug-interactions.html>

Herb-Drug Interaction Chart



General Prescribing Guidelines

- Exercise great caution when prescribing herbs for patients taking drugs with a narrow therapeutic window. These drugs may become dangerously toxic or ineffective with only relatively small changes in their blood concentrations. Examples include digoxin, warfarin, antirejection (immunosuppressive) drugs, many anti-HIV drugs, theophylline, phenytoin and phenobarbital. These patients need to be monitored on a frequent, regular basis.
 - Except where specifically contraindicated, any patient on warfarin taking herbs should have their INR (international normalised ratio) closely monitored, especially when herbal treatment changes.
- Exercise great caution when prescribing herbs for patients taking drugs (these patients need to be monitored on a frequent, regular basis):
 - if heart, liver, or kidney function is impaired,
 - in elderly patients,
 - in pregnant women,
 - in those who are potassium depleted,
 - in those who have received an organ transplant,
 - in those with a genetic disorder that disturbs normal biochemical functions.
- Care should be exercised with patients who exhibit long-term use of laxative herbs or potassium-losing diuretics.
- Critical drugs should be taken at different times of the day from herbs (and food) to reduce chemical or pharmacokinetic interactions. They should be separated by at least 1 hour, preferably more.
- Stop all herbs approximately 1 week before surgery. St Mary's thistle may help reduce the toxic after-effects of anaesthetic drugs, so it can be taken up to the day before, and then again, after surgery.
- Carefully monitor the effects of drugs such as antihypertensives and antidiabetic drugs when combining with herbal remedies. The herbs may make them more or less effective. In the ideal situation the dose of the drug could be adjusted.
- The use of antioxidants (including herbs) in conjunction with chemotherapy and radiotherapy for cancer is controversial. Practitioners should be aware of the issues and make informed recommendations to their patients.
- If more than one of the above cautions apply, and/or if patients are taking more than one drug, additional caution is required.

Further reading:

Mills S, Bone K (eds). *The Essential Guide to Herbal Safety*. Churchill Livingstone, USA, 2005.

* This chart is up-to date as of October 2022. For any questions please contact our Clinical Support clincialsupport@integria.com

Health care professionals please note: when a patient presents using any of the drugs listed below and there is a potential interaction with the herb you intend to dispense, it is important that you or your patient discuss the potential interaction with their prescribing physician before you dispense the herb to the patient.

Drug	Potential Interaction	Basis of Concern	Recommended Action
Bilberry <i>Vaccinium myrtillus</i>			
Warfarin	Potentiation of bleeding.	Herb Alone Antiplatelet activity observed in healthy volunteers (173 mg/day of bilberry anthocyanins). ¹ Case report of postoperative bleeding (bilberry extract undefined). ² Herb or Constituent and Drug Uncontrolled trial (600 mg/day of bilberry anthocyanins + 30 mg/day of vitamin C for 2 months then reduced maintenance dose) of 9 patients taking anticoagulant drugs – treatment reduced retinal hemorrhages without impairing coagulation. ³ Case report (patient reported to consume “large amounts of bilberry fruits every day for five years”). ⁴	Monitor at high doses (> 100 mg/day anthocyanins, low level of risk).
Black Cohosh <i>Actaea racemosa</i> (<i>Cimicifuga racemosa</i>)			
Statin drugs eg atorvastatin	May potentiate increase in liver enzymes, specifically ALT.	Case report. ⁵	Monitor (low level of risk).
Bladderwrack <i>Fucus vesiculosus</i>			
Hyperthyroid medication eg carbimazole	May decrease effectiveness of drug due to natural iodine content. ⁶	Theoretical concern, no cases reported.	Contraindicated unless under close supervision.
Thyroid replacement therapies eg thyroxine	May add to effect of drug.	Theoretical concern linked to a case report where “kelp” caused hyperthyroidism in a person not taking thyroxine. ⁷	Monitor (low level of risk).
Bugleweed <i>Lycopus virginicus</i> , <i>Lycopus europaeus</i>			
Radioactive iodine	May interfere with administration of diagnostic procedures using radioactive isotopes. ⁸	Case report.	Contraindicated .
Thyroid hormones	Should not be administered concurrently with preparations containing thyroid hormone. ⁹	Theoretical concern based on deliberations of German Commission E.	Contraindicated .
Cat's Claw <i>Uncaria tomentosa</i>			
HIV protease inhibitors	May increase drug level.	Case report, in a patient with cirrhosis being evaluated for a liver transplant. ¹⁰	Monitor (low level of risk).
Cayenne (Chili Pepper) <i>Capsicum</i> spp. (See also Polyphenol-containing herbs)			
ACE inhibitor	May cause drug-induced cough.	Case report (topical capsaicin). Theoretical concern since capsaicin depletes substance P. ¹¹	Monitor (very low level of risk).
Theophylline	May increase absorption and drug level.	Clinical study (healthy volunteers, chili-spiced meal). Absorption and drug level lower than during fasting. ¹²	Monitor (low level of risk).

Suplementos

Control de peso

Yeras que actuan como diuréticos

Burdock

Buchu

Dandelion

Cafeína: Té común (common tea), café, yerba mate, mate, gotu kola, guarana, té verde (transitorio)

Chicory

Efedra: ma huang

Hibiscus

Licorice

Parsley

Smilax

Saw Palmetto

Sarsaparrilla

Sunflower

Tribulus terrestris

Posibles efectos tóxico

Foxglove (*digitalis purpurea*)

Juniper

Uva ursi

Whitania

Yervas con función termogénica/anoréxica

- Efedra
- Cafeína
- Yohimbina
- Bitter orange

Estimulan el proceso de termogénesis

Aumento en la velocidad del metabolismo basal en 10%

Durante la termogénesis la grasa corporal es una fuente de energía importante

Efecto anoréxico



Estímulo de la región ventromedial =
saciedad

Yervas con función termogénica/anoréxica

- Efedra
- Cafeína
- Yohimbina
- Bitter orange

Suplementos son combinación de:

Misma yerba: nombres diferentes
Una o más yerbas

Uso sin control (falta de seguridad, utilizar dosis mayores a las recomendadas...)

Arritmia, dolores de cabeza, mareos, infartos cardiovasculares, accidentes cerebro-vasculares

Suplementos para reducción de peso: Sustancias termogénicas

Efedrina y cafeína y aspirina

- mahuang, yellow (white) bark, guarana...
- ✓ efedrina- ↑ liberación norepinefrina → ↑ síntesis de prostaglandina
- ✓ prostaglandina pueden inhibir síntesis de norepinefrina
- ✓ aspirina bloquea acción de la prostaglandina sobre epinefrina → [norepinefrina]

Suplementos para reducción de peso: **Sustancias termogénicas**

Efedrina y cafeína

- ma-huang y guarana, yerba mate, mate, gotu kola..
- Esta combinación tiene mayor efecto en la pérdida de peso/grasa corporal
 - efedrina- ↑ liberación norepinefrina → ↑ liberación de adenosina
 - adenosina inhibe norepinefrina
 - cafeína inhibe adenosina → ↑ [norepinefrina]

“Nutrición Intravenosa”

- Menú: Vitaminas complejo B, amino acidos, glutationa, vitamina C , electrolitos...
- Barrera intestinal: peligro intoxicación.
- Hiponatremia
- Agencia anti-dopaje: prohíbe infusions intravenosas de más de 100 mL (per 12 horas) a menos se tenga TUE (therapeutic use exemption)



Riesgos potenciales (2)

Infección/tromboflebitis

Sangrado/hematoma/ punción arterial

Embolia

Lesiones causadas por personal que pone suero

- 1 Rise of intravenous nutrition products among professional team sport athletes: reasons to be concerned? Doi 10.1136/bjsports-2022-105883
- 2 Givan GV, Diehl JJ. Intravenous fluid use in athletes. Sports Health. 2012 Jul;4(4):333-9. doi: 10.1177/1941738112446285. PMID: 23016105; PMCID: PMC3435915nous (IV) nutrition

Suplementos para aumentar masa muscular

- Alto potencial de ingredientes escondidos
- “protein spiking”



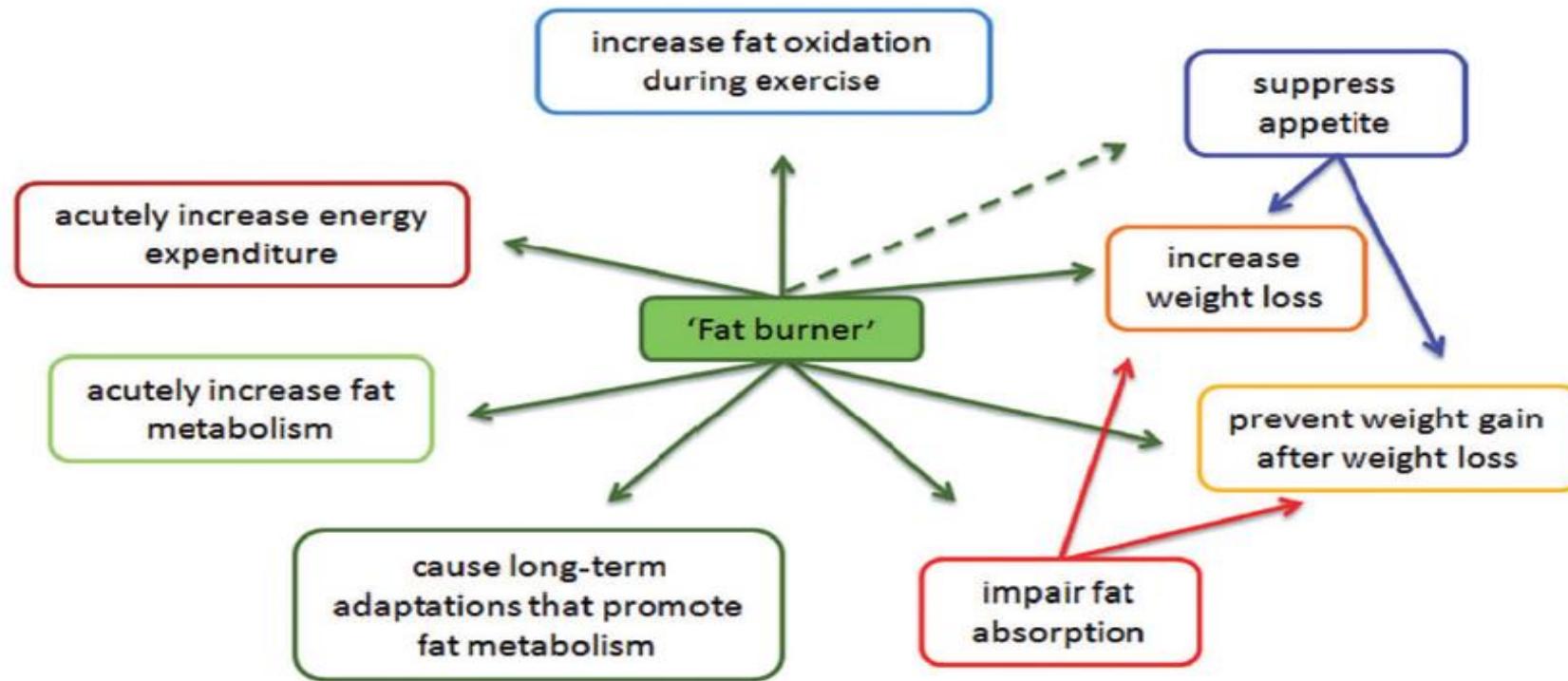


Figure 1 The interaction of 'fat burners' on increasing fat metabolism and promoting weight loss.

Quemadores de grasa

- Jeukendrup AE, 2011

Memoria



Nootropics: ‘cognitive enhancers’ are drugs that some people use in an attempt to improve memory, increase mental alertness and concentration as well as boost energy levels and wakefulness.

<https://adf.org.au/drug-facts/cognitive-enhancers>

Creatina

Uso de la suplementación de creatina ha sido asociado

- Mejorías capacidad de desarrollo fuerza, potencia
- Incrementos en velocidad en carreras de velocidad,
- Proporción de masa libre de grasa
- Reducción en prevalencia de deshidratación y calambres musculares
- Mejorías en la tolerancia en actividades musculares continuas de mas de 150 minutos
- sprint perfo
- Mayor capacidad de aumentar reservs de glucógeno muscular y GLUT 4
- Mejor capacidad de recuperación de lesiones y estres oxidativo inducido por ejercicio

Smith, 2016
Cooper 2012

- Reducir efectos de la Sarcopenia: efectos positivos
- SNC: Concentración endógena de creatina disminuye en SNC con la edad
- Trasportador de creatina puede pasar la BBB (blood brain barrier)
- Enfermedad de Parkinsons: no efectivo
- Huntington's disease: prometedor: se necesita más estudio
- Amyotrophic lateral sclerosis (ALS), o enfermedad de Lou Gehrig's:???
- Memoria a largo plazo: prometedor
- Alzheimer's disease: ???

Smith.2016

Deminice, 2016

<https://medlineplus.gov/druginfo/natural/873.html>

Suplementos mercadeados para mejorar memoria

- Vitaminas del complejo B
- Cafeína
- L-Teanina
- Omega-3
- Vitamina E
- Ginko-Biloba
- Ginseng
- Curcumina
- CDP-Colina

<https://www.webmd.com/brain/ss/slideshow-brain-supplements>:Medically Reviewed by Poonam Sachdev

Table 1. Phytochemicals with potential nootropic effect.

Ref.	Phytochemical Group	Main Active Compounds	Uses and Effects	Botanical Name
[178–182]		Panaxosides (Ginsenosides)	Adaptogen, antioxidant, vasorelaxation	<i>Panax ginseng</i>
[183–187]		Ginkgolides	Antioxidant, neuroprotection, vasodilatation	<i>Ginkgo biloba</i>
[188–190]	Terpenoids	Asiatic acid, centellic acid, madecassic acid, asiaticoside, centelloside, madecassoside, brahmoside	Antioxidant, anxiolytic, nootropic	<i>Centella asiatica</i>
[191–194]		Withanolides	Antioxidant, increase in red blood cell content, nootropic	<i>Withania somnifera</i>
[195–198]		Bacosides, bacopasides	Antioxidant, cognitive enhancer, neuroprotectant	<i>Bacopa monnieri</i>
[199,200]	Alkaloids	Methylxanthines	Anxiolytic, nootropic, panicolytic, stimulant	<i>Paullinia cupana</i>
[201–203]	Polyphenols	Rosavins, salidroside	Adaptogen, antidepressant, antioxidant, anxiolytic, stimulant	<i>Rhodiola rosea</i>
[204–206]		Schisandra lignans	Antioxidant, neuroprotection	<i>Schisandra chinensis</i>
[207–211]	Diverse ¹	Eleutherosides, ciwujianosides	Antioxidant, memory improvement	<i>Eleutherococcus senticosus</i>
[212–214]		Macamides, macaenes	Antioxidant, antidepressant, cognitive enhancer	<i>Lepidium meyenii</i>

¹ Heterogenous group of chemical compounds.

Artritis-Inflamación

Glucosamina

Condroitina

Vit. D

Tumeric

Methylsulfonylmethane (MSM)

S-Adenosyl-L-methionine (SAMe)

<https://www.webmd.com/osteoarthritis/nutritional-supplements-osteoarthritis>
<https://arthritis.ca/living-well/2018/using-supplements-to-treat-arthritis>

Control lípidos en sangre

TABLE 1. Properties of commonly used dietary supplements that are believed to be lipoprotein or lipid-lowering

Supplement	Origin	Proposed Mechanism of Action	Participant Characteristics	Dose/Lipid Effects	Anti-inflammatory Effects	Adverse Effects	Data on ASCVD Outcomes	Expert Opinion/Clinical Recommendation
Red yeast rice	Traditional Chinese medicine	Inhibition of HMG-CoA Reductase	<ul style="list-style-type: none"> Hyperlipidemia (26) statin intolerance (26) ASCVD (26–28, 29) 	At a dose of 1200–4800 mg per day: 14.7%–48.2% ↓ LDL-C, 15%–46.3% ↓ TG, and 0%–17.4% ↑ HDL-C (26)	50% ↓ hsCRP with weighted mean difference of –0.14 mg/L (27, 28)	<ul style="list-style-type: none"> Myalgias Hepatotoxicity 	China coronary secondary prevention study trial showing ASCVD benefit (29)	<ul style="list-style-type: none"> Avoid use in favor of statin therapy when indicated.
Omega-3 fatty acids	Potential cardiovascular benefits reported in observational studies	<ul style="list-style-type: none"> Anti-inflammatory Antioxidant ↓ TG Atherosclerotic plaque stability 	<ul style="list-style-type: none"> Diabetes mellitus (30, 31, 32, 33–36) Hyperlipidemia (30, 31, 32, 33–36) Hypertension (30, 31, 32, 33–36) ASCVD (30, 31, 32, 33–36) 	<p>1. EPA/DHA dose: 0.045–5.9 g/day</p> <p>2. Fish diet: 0.9 to 3.8 servings per week</p> <p>3. Plant-derived omega-3 fatty acids: 0.8 g to about 5 g/day</p> <p>Variable LDL-C effect, 15% ↓ TG, and 7%–12% ↑ HDL-C (31)</p>	↔ effect on CRP (46, 32)	<ul style="list-style-type: none"> Mild GI disturbance Mercury contamination Atrial fibrillation, particularly with higher doses 	<ul style="list-style-type: none"> ↓ ASCVD prior to statins (30, 33) ↔ ASCVD benefit with statin therapy (34–36) 	<ul style="list-style-type: none"> Marine and plant omega-3 fatty acids can be derived from a balanced diet. For the purposes of lipid-lowering, avoid over-the-counter fish oils given the lack of benefit and possible risks of atrial fibrillation and bleeding. Consider icosapent ethyl as an alternative with clinical benefit seen in the REDUCE-IT trial.
Garlic	Culinary agent used in various cultures	Inhibition of HMG-CoA reductase and other enzymes involved with cholesterol synthesis	<ul style="list-style-type: none"> Primarily primary prevention (37) 	<p>1. Garlic powder: 600–5,600 mg/day</p> <p>2. Garlic oil: 9–18 mg/day</p> <p>3. Aged garlic extract: 1,000–7,200 mg/day</p> <p>4. Raw garlic: 4–10 g/day</p> <p>• 2%–11% ↓ LDL-C, 5%–11% ↓ TC</p> <p>• ↔ effect on HDL-C or TG (37)</p>	↓ CRP with mean weighted difference of –0.05 mg/dl (47)	<ul style="list-style-type: none"> Mild GI disturbance Increased bleeding risk 	Not available	<ul style="list-style-type: none"> Avoid concentrated use as a supplement. May be included for spice/flavor as part of a healthy balanced diet, but not for the explicit purpose of lipid lowering and cardiovascular health benefits. Preferentially use statin therapy when indicated.

(continued)

TABLE 1. Continued

Supplement	Origin	Proposed Mechanism of Action	Participant Characteristics	Dose/Lipid Effects	Anti-inflammatory Effects	Adverse Effects	Data on ASCVD Outcomes	Expert Opinion/Clinical Recommendation
Plant sterols	Structurally similar to cholesterol with potential LDL-C effects first identified in 1950	Inhibits intestinal absorption of cholesterol	<ul style="list-style-type: none"> Hyperlipidemia (38, 39) Metabolic syndrome (38, 39) Obesity (38, 39) ASCVD (39) 	<ul style="list-style-type: none"> Plant sterol dose 0.19 to 9.0 g/day 8.3% ↓ LDL-C ↔ effect on HDL-C or TG (38) 	↔ anti-inflammatory effects (39)	No major reported adverse effects	Not available	<ul style="list-style-type: none"> May serve as an adjunct to a heart healthy diet. However, modest lipid lowering so clinicians should take time to set realistic expectations. Avoid in patients with suspected beta sitosterolemia. Preferentially use statin therapy when indicated
Cinnamon	Southeast Asia Spice	<ul style="list-style-type: none"> Antioxidant, Anti-inflammatory ↓ glycogen synthesis, glycogenolysis, glucose absorption 	<ul style="list-style-type: none"> Diabetes mellitus (40, 41) Hyperlipidemia (40, 41) Obesity (41) 	<ul style="list-style-type: none"> 1. Cinnamon powder: 1–6 g of per day 2. Spray-dried water extract of cinnamon: 500 mg per day 3. Ground cinnamon: 20g per day. 0%–31% ↓ TG ↔ effects on HDL-C or LDL-C (40) 	<ul style="list-style-type: none"> ↓ CRP with weighted mean difference of –0.22 mg/dl (41) 	<ul style="list-style-type: none"> Mild GI disturbance Hepatotoxicity 	Not available	<ul style="list-style-type: none"> Avoid concentrated use as a supplement. May be included for spice/flavor as part of a healthy balanced diet, but not for the explicit purpose of lipid lowering and cardiovascular health benefits. Preferentially use statin therapy when indicated.
Turmeric	Southeast Asia Spice	<ul style="list-style-type: none"> Anti-inflammatory Antioxidant ↑ insulin sensitivity 	<ul style="list-style-type: none"> Hyperlipidemia (42–44, 45) Diabetes mellitus (42–44, 45) Hypertension (42–44, 45) Obesity (42–44, 45) Inconclusive data (42–44) 	Purified curcumin or a curcuminoid mixture, extracts with determined content of curcumin or curcuminoids, or turmeric powder, regardless of dosage and frequency	↔ effect on CRP (45)	Mild GI disturbance	Not Available	<ul style="list-style-type: none"> Avoid concentrated use as a supplement. May be included for spice/flavor as part of a healthy balanced diet, but not for the explicit purpose of lipid lowering and cardiovascular health benefits. Preferentially use statin therapy when indicated.

ASCVD, atherosclerotic cardiovascular disease; GI, gastrointestinal; TC, total cholesterol; TG, triglyceride.

TABLE 2. Comparison of recent trials investigating the effect of prescription omega-3 fatty acids on cardiovascular outcomes

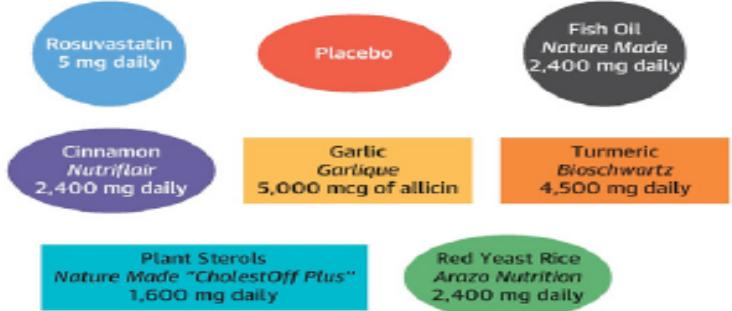
Study Name	Year	Sample Size	Follow-Up (years)	Population	Intervention	Control	Primary Endpoint	Adverse Effects
JELIS (67)	2007	18,645	4.6	Hyperlipidemia (LDL-C \geq 170 mg/dL)	EPA 600 mg TID ^a + statin ^b (open label)	Statin ^b	↓ Major coronary events (2.8% vs. 3.5%, P = 0.011)	↑ Gastrointestinal disturbance (3.8% vs. 1.7%, P < 0.0001) ↑ Skin rash (1.7% vs. 0.7%, P < 0.0001) ↑ Bleeding (1.1% vs. 0.6%, P < 0.0006)
REDUCE-IT (68)	2019	8,179	4.9	ASCVD or diabetes and other risk factors, on statin therapy + TG level 135–499 mg/dL	Icosapent ethyl 2G BID (Highly purified EPA)	Mineral oil	↓ Composite primary cardiovascular outcome HR, 0.75; 95% CI 0.68 to 0.83; P < 0.001	↑ Atrial fibrillation or flutter (3.1% vs. 2.1%, P = 0.004) ↑ Serious bleeding (2.7% vs. 2.1%, P = 0.06)
VITAL (66)	2019	25,871	5.3	Primary prevention cohort of men \geq 50 years of age and women \geq 55 years of age	Marine omega-3 fatty acid 1G per day (combination EPA/DHA) ^Ψ	Olive oil	↔ In major adverse cardiac events (a composite of myocardial infarction, stroke, or death from cardiovascular causes). Hazard ratio, 0.92; 95% CI, 0.80 to 1.06; P = 0.24.	↔ in gastrointestinal symptoms, major bleeding episodes, or other serious adverse events
EVAPORATE (69)	2020	80	1.5	Coronary atherosclerosis by MDCT, on statin therapy and TG level 135–499 mg/dL	Icosapent ethyl 2G BID (Highly purified EPA)	Mineral oil	↓ In coronary low attenuation plaque volume (-17% vs. +109%, P = 0.0061)	↑ Atrial fibrillation (5.3% vs. 3.9%, P = 0.003)
STRENGTH (70)	2020	13,078	3.4	High cardiovascular risk, hypertriglyceridemia, and low levels of HDL-C (LDL-C \leq 100 mg/dL or TG 180–500 mg/dL and HDL-C < 42 mg/dL for men and < 47 mg/dL for women)	Omega-3 carboxylic acid 4G Daily. (combination EPA/DHA)	Corn oil	↔ Difference in the composite primary cardiovascular outcome (12.0% vs. 12.2%, P = 0.84)	↑ Gastrointestinal disturbance (24.7% vs. 14.7%, P < 0.05) ↑ Atrial fibrillation (HR 1.69, 95% CI 1.29–2.21, P < 0.001)
OMEMI (71)	2020	1,027	2.0	Patients aged 70–82 years with recent (2–8 weeks) acute myocardial infarction	Combination EPA 930 mg, DHA 660 mg 1800 mg Daily	Corn oil	↔ Composite of nonfatal AMI, unscheduled revascularization, stroke, all-cause death, heart failure hospitalization (21.4% vs. 20.0%, P = 0.60)	Borderline ↑ in atrial fibrillation (7.2% vs. 4.0%, P = 0.06) ↔ major bleeding (10.7% vs. 11.0%, P = 0.87)

^Ψ 1 g per day as a fish-oil capsule containing 840 mg of omega-3 fatty acids, including 460 mg of EPA and 380 mg DHA.^aCapsules that contained 300 mg of highly purified (>98%) EPA ethyl ester (Mochida Pharmaceuticals, Tokyo, Japan).^bPravastatin 10–20 mg or simvastatin 5–10 mg.

CENTRAL ILLUSTRATION: SPORT Study With Individual Participant Percent Change in Low-Density Lipoprotein Cholesterol

Primary Prevention
40 to 75 years of age
LDL-C between 70 and 189 mg/dL
10-year ASCVD risk between 5% and 20%

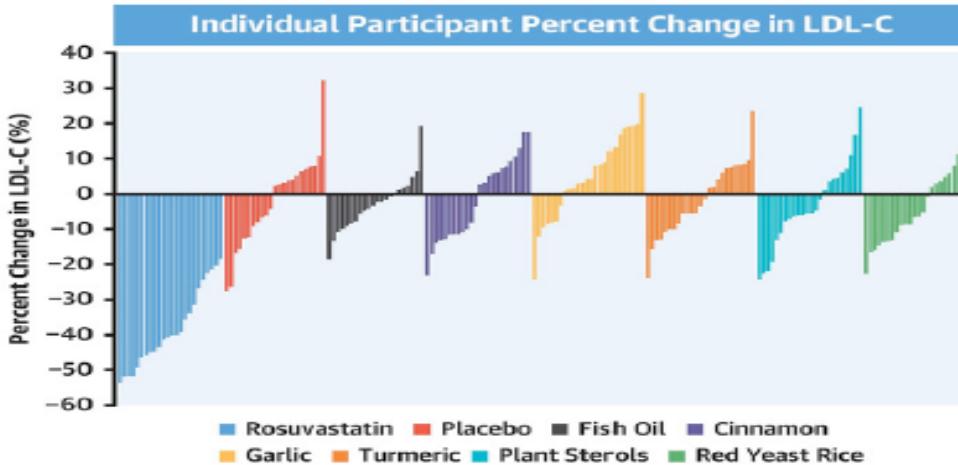
Randomized to one of the following:



Rosuvastatin Decreased LDL-C, Total Cholesterol, and Serum Triglycerides Significantly More Than Placebo and Each Supplement



No difference in LDL-C reduction with any supplement compared to placebo



Laffin LJ, et al. J Am Coll Cardiol. 2023;81(1):1-12.

Diabetes Tipo 2

Acido Alfa-lipoico

Berberine

Magnesio

Suplementos herbarios

Cromio

Omega-3

Selenio

<https://www.nccih.nih.gov/health/diabetes-and-dietary-supplements-what-you-need-to-know>

Profesionales de la salud y suplementos nutricionales

Evidencia confiable

Orientación al cliente

Proceso abrumador y de alto riesgo

Trabajo en coordinación con otros profesionales de la salud:
nutricionistas/dietistas licenciados



Article

Pharmacists' Perceptions on Nutritional Counseling of Oral Nutritional Supplements in the Community Pharmacy: An Exploratory Qualitative Study



Dificultades al momento de orientar

- Una hierba: multiples nombres
- No podemos asegurar que la cantidad que dice la etiqueta es igual a la que tiene el servicio sugerido para consumo
- No sabemos si el producto contiene los ingredientes que dice la etiqueta
- No sabemos si el producto ha sido adulterado
- “Proprietary Blends”: **MUCHA** precaución

¿Dónde buscar información? Seguridad/Uso del Producto

- American Herbal Association: \$
- Natural Medicines Comprehensive Database: \$
- NIH, Office of Dietary Supplements
- NIH, National Center for Complementary and Alternative Medicine
- The National Center for Complementary and Integrative Health (NCCIH)
- The National Institutes of Health (NIH) Office of Dietary Supplements (ODS),
- Medline Plus:
 - http://www.nlm.nih.gov/medlineplus/druginfo/herb_All.html
 - <http://www.usada.org/substances/supplement-411/>
- Consumerlab.com \$
- Examine.com
- NSF.com
- NCAA.com
- United State Pharmacopedia
- Aegis shield.com
- Cologne List.com(list<http://www.koelnerliste.com/en/cologne-list.html>)

Laboratorios

- U.S.Pharmacopedia
- Consumerlab.com
- Cologne List.com
- NSF.com
- Informed



Reporte de suplementos y efectos adversos

Safety Reporting Portal

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Resumen

- Los suplementos nutricionales, al igual que los medicamentos, tienen sustancias activas(sustancias química) que impactan tejidos, y pueden alterar la eficacia de algún medicamento.
- Hay mucha pseudociencia que desvirtua las definiciones y conceptos.
- La Industria de los suplementos nutricionales es poderosa y carece de regulación.
- Inseguridad entre el contenido del producto y lo que se menciona en la rotulación nutricional.
- Debemos utilizar referencias profesionales para investigar sobre los “ingredientes que aparecen en la etiqueta”.
- Desgraciadamente, posibilidad de fraude en un suplemento es real.
- Hace falta más control y regulación.



Post-prueba

Dietary supplements are:

- A Innocuous products that could improve general health.
- B Articles intended for use in the diagnosis, cure, mitigation and treatment or prevention of disease in man or other animals.
- C Products (other than tobacco) intended to supplement the diet .

Innocuous: inoffensive, harmless, safe

Post-prueba

Which of the following claims can not be marketed on the label of a dietary supplement.

- A *Explicit or implied disease claims, unless they meet an exception*
- B *General weel-being claims*
- C *Claims to affect the structure or function of the body*

Post-prueba

A dietary supplement can be tainted (intentional or unintentional) with drugs

- A True
- B False

Dietary supplements can potentiate or interfere with some medications used for approved medical treatment

- A True
- B False

Post-prueba

Consumers can trust 100% on the ingredients content and amounts that are described in the label.

A Yes

B No

The FDA requires 10 years of research before a nutritional supplement can be sold.

- A True
- B False

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