

What you must know about Dietary Supplements and its Legal Regulations

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Abstract

Dietary supplements are not drugs to treat diseases but are products intended to supplement diets. They are vitamins, minerals, amino acids, proteins, enzymes, metabolites, herbal/botanical plants and many others. Some supplements play an important role in health such as calcium and vitamin D to keep bones strong [1], and folic acid for pregnant women to prevent certain birth defect in new born children [2]. Dietary supplements are marketed in the form of tablets, capsules, soft gels, gel caps, powders, drinks and energy bars. There is no need for dietary supplements to be approved by the U.S. Food and Drug Administration (FDA) before marketing as in the case of prescription and over counter drugs, but dietary supplements manufacturers are responsible to register their manufacturing facilities with FDA and to demonstrate that their manufactured products are safe and label claims are not misleading.

Dietary Supplements Health and Education Act (DSHEA) were passed by United State Congress in the year 1994 to provide a regulatory framework for the safety of dietary supplements.

Keywords: *Dietary Supplements; Dietary Supplements Ingredient; Herbal Supplements; Botanical Supplements; DSHEA; FDA; TCA; GMP*

Introduction

Dietary supplements both naturally or synthetic chemicals are products intended to supplement nutrients or may have health benefits and are taken by mouth in different forms (pills, capsules, tablets or liquid). Dietary supplements are nutrient compounds includes vitamins, minerals, fibers, fatty acids, proteins/amino acids, and substances extracted from plants such as pigments or polyphenols [3], from animals such as collagen [4], from fish such as omega-3-fatty acids [5] and from bacteria or molds such as metabolites [6] and enzymes [7]. These ingredients of dietary supplants are sold individually or in combination. In United States there are over 50,000 marketed dietary supplements consumed daily by over 50% of American population. Multivitamins and menials are the most commonly consumed dietary supplements especially for people failed to consume a balanced diet. The total market size of dietary supplements in North America alone was estimated in the year 2016 for about \$37 billion [8] and is rising due to the awareness towards calorie reduction, weight loss, and the expectation that these dietary supplements promote health and wellness.

Dietary Supplements Health and Education Act (DSHEA) [9] were passed in the year 1994 by United States Congress to provide a regulatory framework to assure the safety of marketed dietary supplements. Dietary supplements were defined by DSHEA a product (other than tobacco) intended to supplement the diet and must be labeled as dietary supplements. DSHEA granted the United States Food and Drug Administration (FDA) the authority to establish dietary supplement regulations, for manufacturing, health claims, labeling and to encourage research on these supplements. Plus, DSHEA gave to Federal Trade Commission (FTC) a division of FDA the authority to regulate dietary supplements advertising.

It is against United States Federal regulations for dietary supplements manufacturers to claim that their products prevent or treat any disease but allowed them to use the word structure or function if there is a scientific evidence for a supplement providing potential health effect. The FDA enforces these regulations, and prohibits the sale of dietary supplements or ingredients that are harmful, or not manufactured according to Good Manufacturing Practices (GMPs) standard.

Similar to food manufacturers there is no need for government approval to manufacture or sell dietary supplements, and there is no required clinical trials to be sold as pharmaceutical drugs. Dietary supplements manufacturers have the responsibility not the government to confirm the safety of their finish products.

In summary dietary supplements regulations are different than the regulations of conventional foods and pharmaceutical drugs. The FDA role for dietary supplements begins after the product enters the market place and have the authority to remove any dietary supplement from the market if demonstrated to be unsafe.

Dietary supplements

Multivitamins and minerals

Vitamins and mineral supplements are defined in U.S. as: "supplements containing three or more vitamins and minerals that does not include herbs, hormones or drugs [10].

Vitamins are supplements that people used to boost their energy level, and some minerals plays role as enzymes cofactors in metabolic pathways for energy.

Vitamins are classified into water and fat soluble as following:

- a. Water soluble vitamins: are vitamins B complex [11] and vitamin C [12]. Vitamin B complex are a mixture of eight essential vitamins of Thiamin (B_1), Riboflavin (B_2), niacin (B_3), Pyridoxine (B_6), Pantothenic acid, Folic acid, Cyanocobalamin (B_{12}), and Biotin. Vitamin C, (L-ascorbic acid), is present in some foods, and available as a dietary supplement. Unlike most animals, human is unable to synthesize [13] vitamin C so it is an essential in our diet for the biosynthesis of collagen, L-carnitine, and certain neurotransmitters; plus, it is antioxidant and plays role in protein metabolism. Soluble vitamins are secreted from the body and there is no toxicity concern when consumed at higher daily dose.
- b. Fat soluble vitamins: are, A, D, E, and K. are capable to be stored in the body and pose a greater risk for toxicity when consumed at higher daily dose [14]. Vitamin A, is an important antioxidant that may play role in certain cancer prevention, and helping eyes adjust to light. Vitamin A also, plays role in bone growth, tooth development, reproduction, cell division, gene expression, and the regulation of immune system [15]. Vitamin D function is to help the body' utilize calcium and phosphorous [16] by increasing the small intestine absorption rate of these minerals, to maintain healthy bones. Vitamin D also play role in immune system and in controlling cell growth. Vitamin E is an antioxidant, protecting red blood cells (RBC), and essential fatty acids from destruction [17] Vitamin K plays an essential role in normal blood clotting, promoting bone health, and helping proteins biosynthesis for blood, bones, and kidneys [18].

Minerals does not provide energy or calories for the body, but are needed in small amounts to keep healthy body, and for other functions such as enzymes activity. Human body does not synthesize minerals, and must be obtained from foods, or from dietary supplements. These minerals are Ca, Mg, Cr, Zn, Se, K, Fe, Mn, I, P, and Cu. Calcium (Ca) function is to keep bones and teeth strong and, supporting skeletal structure. Calcium also, play roles in cell signaling, blood clotting, muscle contraction and nerve function [19]. Iron (Fe) is an essential element for red blood cells production (hemoglobin) and muscle cells structure (myoglobin) [20].

Vitamins and minerals supplements have health impacts for some people for example. Pregnant women should take 10 µg of Vitamin D per day during the pregnancy and breast feeding, to maintain proper levels of calcium and phosphorus [21] in their body, and should take 400µg of folic acid during the first trimester of pregnancy, to prevent birth defect [22]. Some women need to take iron, vitamin C, or calcium during pregnancy only by doctor advice.

Global market of vitamins and minerals is over \$9 billion per year [23] and are available in the market in packages contain at least 10 vitamins and 10 minerals with the recommended 100% daily value (DV) and below the tolerable dose as determined by FDA.

Fibers

Health benefits from fibers intake, including normalizing bowel function and preventing constipation. The source of fibers in dietary supplements, includes Psyllium, methyl cellulose, seed husk, or fiber extracted from fruits and vegetables. Consumption of fibers may lower blood cholesterol, alleviate irritable bowel syndrome, reduce the risk of colon cancer, and increase feelings of satiety [24]. However, over consumption of fibers could lead into fluid imbalance, dehydration, minerals deficiencies, nutrients deficiencies, drug interactions and other medical problems [25]. To avoid such implications, the American Dietetic Association (ADA) recommends that the average adult consume about 25 to 38 grams of dietary fiber per day [26]. The current global market of dietary fibers are about \$3 billion per year [27].

Fatty Acids

Essential fatty acids, are polyunsaturated short carbons chain that our body cannot synthesize and must ingested for good health. The two known polyunsaturated fatty acids that essential for human are alpha-linolenic acid (ALA) and linoleic acid. The body convert alpha Linolenic acid (ALA) into omega-3 fatty acid (ω -3) [28] and convert linoleic acid(LA) into omega-6 fatty acid (ω -6) [29]. According to Food and Drug Administration (FDA) the use of omega-3 fatty acid (ω -3) supplements are safe, but recommended that the intake should not exceed 2,000 mg/day to avoid blood thinning or bleeding [30] it is recommended that People planning for surgery should stop taking omega-3-fatty acid (ω -3) a week or two before the surgery [31]. These essential fatty acids help reducing inflammation, critical for cell signaling and necessary for the production of hormones and neurotransmitters. Selecting of right fatty acids in dietary supplement could help in improving a range of health conditions such as cardiovascular, diabetes and neurological function.

Conjugate fatty acids (CFA) is an isomer of linoleic acid (LA) and are naturally present in meat and dairy products. Average daily intake of conjugated fatty acids for most people is less than one gram per day mainly from meat and dairy products [32]. Conjugated fatty acids in dietary supplement is manufactured from sunflower oil and from other vegetable oils and marketed with claims to build muscle, burn fat, and as antioxidant/anti-cancer. The recommended daily intake of conjugated fatty acid is about 3 - 5 gram per day even there is insufficient evidence that conjugated fatty acids has health benefit as being claimed especially for overweight or obesity. Further studies for the evaluations of physiological bioactivity of conjugated fatty acids on lifestyle-related diseases in humans and animals are necessary.

Protein and amino acids

Protein is amino acids linked together in a chain by peptide linkages and is one of the three macronutrients for energy (carbohydrates, proteins, and fats). The three common protein supplements are whey, soy and casein, marketed in fruit flavored and in the form of powders, cookies, cream, and bars and generally fortified with vitamins and minerals Protein supplements claims are to improve muscle growth, increase body weight gain, increase lean muscle mass, and increase strength and power.

Amino acids are primary source of nitrogen for the body and are essential source for muscle growth, immune systems, enzymes, and hormones, plus amino acids play role in balance blood PH level [33]. Amino acids are classified into two categories: Essential amino acids that cannot be synthesize in the body and must obtained from foods or from dietary supplements. These essential amino acids are phenyl alanine, threonine, methionine, tryptophan, lysine, leucine, isoleucine, and valine. The rest of known 20 amino acids are non-essential

amino acids.

Protein supplements should contain most of the essential amino acids and consumers should review amino acids profile on the package label especially for essential amino acids and for branched chain amino acids (BCAAs). Branched chain amino acids are leucine, isoleucine and valine. The daily requirement intake of leucine is 40 milligram per kilogram body weight, and for both isoleucine and valine daily requirements intake is 10 - 30 milligram per kilogram body weight for each. Protein supplements claims including branched chain amino acids (BCAAs) is for stimulating the synthesis of muscle proteins.

Marketed protein supplements contain about 20 - 30 grams of protein per serving and It is important to highlight that high dose of daily protein intake could have side effects such as: nausea, thirst, bloating, cramps, fatigue, headache, reducing appetite and increasing bowel movements [34].

L- Glutamine supplement

L-Glutamine is one of the 20 building block amino acids in proteins and is the major amino acid in body muscles protein, making about 61% of skeletal tissue [35]. L-Glutamine is not essential amino acid, but it can be essential in the time of intense athletic training or in the case of gastrointestinal disease. Bodybuilders should take about 10 to 15 grams of L-glutamine per day [36]. To minimize breakdown of muscle during exercise and to improve protein metabolism. L-Glutamine has no side or adverse side effects, because it is naturally occurs in the body.

Creatine supplement

Creatine is a nitrogenous organic chemical compound synthesized by the body muscle motions and is marketed as a supplement for athletics. Creatine supply body cells with energy in the form of Adenine Tri Phosphate (ATP). The recommended maintenance dose of creatine for athletes is in the range of 5 to 10 grams per day [37]. Creatine is marketed in the form of monohydrate, ethyl, hydrochloride, magnesium chelate, malate, nitrate and gluconate. Creatine supplement claims for athletics are to improve muscle growth, improve muscle function, Increase lean muscle mass, increase weight gain, increase energy production for exercise performance, delayed fatigue during exercises, and improve recovery after exercises. Patients with kidney disease, high blood pressure, or liver disease should not use creatine as dietary supplement [38] and should consult with a physician before taking creatine supplement with medications.

Herbal supplements

Herbal plants includes flowers, leaves, bark, fruit, seeds, stems, roots, or mixtures are used for medicinal purpose for thousands of years. Currently, herbal supplements, sometimes known by the name botanical supplements are sold as fresh, dried; liquid extracts; tablets, capsules, powders; tea bags; and in other forms. Total sale of herbal supplements is \$7.5 billion per year in United States alone with growing market rate of 8% per year [39]. Herbal supplements can have drug-like effects range from mild to powerful, for example, Chamomile and Peppermint, are used for digestion and considered safe [40] with mild action. Herbal supplement Kava reported to have an immediate powerful action affecting anxiety and muscle relaxation [41].

Herbal supplements are not regulated as prescription or over the counter drugs and does not have the same scientific scrutiny, but manufacturers must follow Good Manufacturing Practices (GMP) to ensure that they are consistently manufactured and meet quality standards.

Food and Drug Administration (FDA) considers some herbal supplements are worthless or unsafe. Some concerns about the safety of herbal supplants because they are unregulated, may contain additives or contaminants, may cause allergic reaction, may interact with conventional drugs, can be mislabeled, and can be toxic if used at high dose.

Ginseng: Refers to the roots of Asian plant *Panax ginseng*. The active chemical compound in this plant that is being studied for potential use in medicine is ginsenoside ($C_{42}H_{72}O_{14}$). Although the health benefits of ginseng is questionable, by western scientists it has become one of the most popular herbal supplement in the world with recommended daily intake 100 - 300 milligram per day. Its beneficial claims are for energy boost, lower blood sugar, lower cholesterol levels, relieves stress, promote relaxation, and treat sexual dysfunction in men. Ginseng as dietary supplements should be standardized to contain about 4 - 5% of the active chemical compound ginsenoside [42].

Ginkgo: The plant *Ginkgo biloba* is the best-selling herbal supplements in United States. There are about 40 chemical compounds in Ginkgo plant and only two of these compounds are biologically active as medicine. These two active chemical compounds are flavonoids and terpenoids. Flavonoids are antioxidants, with claims to protect nerves, heart muscle, blood vessels, and retina from damage [43]. Benefit claims for Terpenoids are to improve blood flow and reducing the stickiness of platelets [44]. Some research studies suggested that Ginkgo might help people with Alzheimer. The recommended daily intake of Ginkgo supplements is in the range of 120 to 240 milligrams per day divided into 24 - 32% flavonoids and 6 - 12% terpenoids. Ginkgo supplements may interact with prescription or over the counter drugs and consulting a physician is recommended.

Hydroxyl citric acid: Hydroxyl citric acid ($C_6H_8O_8$) is a derivative of citric acid extracted from pumpkin-like plant *Garcinia cambogia*. *Garcinia* plant contains about 50% Hydroxyl citric acid (HCA). This active chemical compound claims to promote weight loss (suppress appetite), store energy in the form of glycogen, reduce blood lipids synthesis (cholesterol) and increase fat oxidation [45]. There is no adverse side effects associated with hydroxyl citric acid (HCA) as herbal supplement and its recommended intake for weight loss is about 1,200 milligrams per day.

Enzymes

Enzymes sources as dietary supplements are from animals such as pepsin, trypsin and chymotrypsin, from plants such as bromelain, papain, and diastase, and from microbial such as amylases, proteases, and lipases. Most enzymes supplements commercially used as digestive aids and marketed in mixture forms of multiple enzymes with international standard enzymatic activities. Enzymes can be combined with herbals (botanicals) or other dietary supplements.

Coenzyme Q₁₀

Coenzyme Q₁₀ (CoQ₁₀) is powerful natural antioxidant found in many foods, and is also available as dietary supplement. It is fat-soluble, present in mammalian cells (mitochondria), participates in metabolic pathways which generates energy in the form of ATP. It is also act as antioxidant helps fight cells damage from free radicals [46]. High concentration of CoQ₁₀ found in vital organs that require high energy, such as heart, liver, and kidney and it is also found in foods such as meat, fish, and leguminous plants. Daily intake of CoQ₁₀ from food sources is about 3 - 6 milligrams per day. CoQ₁₀ has become a popular natural supplement produced from yeast with claims to boost energy and stabilize cholesterol, and many other health benefits.

Antioxidants

Antioxidants inhibits oxygen oxidation of other molecules into free radicals. Free radicals (atoms with an odd number of electron) in the body may damage cells and even increase the risk of cancer [47]. Human body naturally produce antioxidants such as glutathione and enzymes (catalase and superoxide dismutase). The source of antioxidants intake are from foods or dietary supplements of beta-carotene, vitamins A, C, and E.

Metabolites

Primary metabolites, are intermediate small chemicals substances found inside cells from metabolic pathways, it can be recognize and acted upon by enzymes. Primary metabolites are able to enter into subsequent reactions, have a finite half-life; do not accumulate inside cells, control metabolism, and have useful biological functions in cells. Secondary metabolites are organic compounds that secreted as

waste and have no health benefits. Primary metabolites are used with other dietary supplements to improve physical needs and assist the body in maintaining better balance.

Examples for primary metabolites are:

- a. **Pyruvate:** Pyruvate is a natural substance in the body generated from carbohydrates metabolic pathway [48]. Calcium pyruvate ($C_6H_6CaO_6$) is the pyruvate supplement that is used for weight-loss and its recommended intake is about 5 grams per day.
- b. **Glucosamine sulfate:** ($C_6H_5NO_9S$) is naturally present in the body for building tendons, ligaments, and cartilage, plus, it is the thick fluid that surrounds joints [49]. Glucosamine sulfate supplement is used for osteoarthritis and its recommended intake about 1000 to 2000 milligrams per day [50].

Dietary Supplements Regulations in united states

Dietary supplements contains dietary ingredients that intended to supplement the diet and are defined as products taken by mouth. Before the year 1990, Food and Drug Administration (FDA) regulated dietary supplements that only contains essential nutrients to protect public from mislabeling and unsafe products. In the year 1990 Nutrition Labeling and Education Act included herbs as dietary supplements, and in the year 1994, Congress passed the Dietary Supplements Health and Education Acts (DSHEA) a legislation provided regulatory framework for assuring the safety of dietary supplements.

Dietary Supplements Health and Education Acts (DSHEA) expanded the definition of dietary supplements beyond essential nutrients and herbs and granted the U.S. Food and Drug Administration (FDA) the authority to regulate dietary supplements processing, health claims, and labeling, plus created governmental bodies to encourage research on dietary supplement ingredients and product's label claims.

In summary DSHEA recommendations are [51]:

- a. No need for dietary supplements manufacturers to receive FDA approval before marketing their products.
- b. In the case of new ingredients for a dietary supplement, a notification must be submitted to FDA for approval with evidence of safety or expectations of safety.
- c. Dietary supplements manufacturers and distributors are responsible to meet DSHEA, and FDA all safety and labeling requirements before marketing their products.
- d. The role of FDA authority on dietary supplements begins after the product enters the marketplace.
- e. Dietary supplement manufacturers and distributors are responsible to inform FDA with any serious adverse events that are reported to them by consumers or health care professionals on their marketed products
- f. It is illegal to market dietary supplements for treatments, cure specific diseases, or to alleviate the symptom of a disease.
- g. Labeling claims for dietary supplements are allowed as long it does not diagnose, prevent, treat or cure diseases.
- h. FDA is responsible for dietary supplements labeling claims, including packaging, inserts, and other promotional materials distributed at the point of sale.
- i. Federal Trade Commission (FTC) is responsible for dietary supplements advertising, including prints, broadcast ads, catalogs, and any similar direct marketing materials.
- j. All dietary supplements claims must meet both FDA and FTC requirements.

Dietary supplements claims that are authorized by FDA based on scientific literature review are [52]:

- Calcium and osteoporosis.
- Sodium and hypertension.
- Folic acid and neural tube pregnancies.
- Fibers and cancer.
- Fruits and vegetables and cancer.
- Dietary fat and cancer.
- Soy protein and coronary heart disease.
- Omega-3-fatty acids and heart disease
- Saturated fats and cholesterol and coronary artery disease
- Sugar alcohols and dental caries
- Vitamins B (folic acid, B₆, and B₁₂) and heart disease.

Domestic and foreign manufacturers of dietary supplements are responsible to apply Good Manufacture Practice (GMP) for their production process, packaging, labeling and distribution. Dietary supplements manufacturers are also responsible to ensure that their quality control systems are in place, by establishing standard protocols for extraction, and production process, developing standard specifications for both raw materials and finish products, developing valid chemical and microbial test methods for the detection of pesticides, herbicides, fertilizer, and harmful microorganism., developing shelf life and storage conditions for each product, and having reliable documentation system to track each batch of ingredients and finished products.

GMP requirements for dietary supplements are [53]:

- Design plants that easy facilitate maintenance and cleaning.
- Develop Hazard Analysis Control Points (HACCP) for each dietary supplant production process.
- Employ qualified employees and supervisors.
- Having proper standard manufacture operations.
- Having quality control procedures.
- Testing all incoming process ingredients, and final products.
- Store dietary supplement ingredients under proper conditions.
- Store and distribute finish products of dietary supplements under appropriate conditions such as temperature, humidity, light, and sanitation to protect and assure products quality and activity.
- Maintain records keeping for one year past the shelf life date or for two years after the distribution of last batch of dietary supplement.
- Must have a proper handling of consumer complains.

Dietary supplements manufacturers are also responsible to have a valid good sanitation practice for product and non-product contact surfaces. Include developing periodic sanitation protocol and verification system for the effectiveness of their sanitation protocols.

Labels and advertise regulations [54]

Labels on dietary supplement packages should listed accurate quantity of contents, complete list of ingredients, ingredients safety information, the part of plant used in the case of herb supplements, and list of nutrition information including serving size, and percentage

of daily value (DV). Labels information should show, the name and place of the business, and a disclaimer stated that “this product is not intended to diagnose, treat, cure, or prevent any diseases”.

Advertising including prints, broadcast ads, catalogs, and any other marketing materials are under the responsibility of Federal Trade Commission (FTC) to make sure that dietary supplements claims are supported by sound scientific evidence.

Discussion

Dietary supplements are available in different forms such as pills, capsules, powders, tablets or liquids and can be purchase without a physician prescription. More than 50% of American population are taking daily or occasion one or more dietary supplements to make sure that they are getting enough essential nutrients and to maintain or improve their health. Majority of Americans consumers do not need to take these dietary supplements because, they are getting all of required nutrients from eating a variety of healthy foods.

In United States there are over 50,000 marketed dietary supplement and some of these dietary supplements have side effects, when they are taken with prescription or over counter drugs. Plus, dietary supplements could have side effects for people with health conditions, and consultations with health care providers or physicians are always recommended.

The most popular dietary supplements are multivitamins and minerals. As an examples, evidence suggested that the intake of calcium in dietary supplement supports bone health, and the intake of vitamin D with calcium in dietary supplement helps the body to absorb calcium. Evidence suggested that both vitamins C and E are antioxidants preventing cell damage from free radicals and maintain the body in good health. Iron in dietary supplement is needed for women during pregnancy, and breastfed infants, to prevent anemic due to blood loss. The daily intake of 400 micrograms folic acid in dietary supplement is important for all women of childbearing age to prevent birth defect. Research evidence suggested that vitamin B₁₂ keeps nerves and blood cells healthy [55] and the main source of vitamin B₁₂ is from the daily intake of meat and dairy products. In the case of vegetarians they should consider taking vitamin B₁₂ as dietary supplement to make sure of getting vitamin B₁₂ health benefits.

Dietary supplement of fish oil a source of omega-3-fatty acids (ω -3) can promote healthy heart and most scientific evidence support omega-3-fatty acids (ω -3) health benefits. Recommended daily intake of omega-3-fatty acid (ω -3) should not exceed 2,000 milligrams per day to avoid blood thinning or bleeding. Patients going for surgery should stop taking dietary supplement of omega-3-fatty acids (ω -3) for a week or two before the surgery as recommended by health professions and physicians.

Despite the important of plants in medicine, FDA considers some herbal remedies are worthless or harmful because herbal supplants are unregulated, sometime mislabeled, may contain additives or contaminants, may cause allergic reaction, may interact with prescription or over counter drugs, and can be toxic if used at high dose.

As an example for such concerns, the herbal plant *Hypericum perforatum* a native plant of Europe and Asia is marketed under trade name St. John's wort [56] with claims for the treatment of anxiety, mild depression, stomach upset, insomnia, fluid retention, and hemorrhoids. Plus it is used topically for the treatment of nerve pain, muscle pain, skin inflammation, skin wounds, and burns. St. John's wort has gastrointestinal side effects at high dose, such as nausea, abdominal, loss of appetite, and diarrhea, plus it can be life-threatening supplement when interact with verities of prescription drugs. St. John's wort is not evaluated or regulated by FDA for safety, effectiveness, or purity.

Before 1994 Food and Drug Administration (FDA) only protected the public from mislabeled and unsafe dietary supplements of essential nutrients by using the same food regulations. In 1994 Dietary Supplement Health and Education Act (DSHEA) was created and expanded the definition of dietary supplements beyond essential nutrients and no longer considered dietary supplements as food additives. This new definition, exempt dietary supplements from prescreening for safety and efficacy studies before released into market. These marketed dietary supplements are different in regulations from prescription and over-the-counter drugs that must be approval by FDA

before marketing, Dietary supplements manufacturers do not need to provide evidence of safety and efficacy to FDA before marketing their products, but they must follow certain Good Manufacturing Practices (GMP) to ensure the identity, purity, strength, and composition of their marketed dietary supplements. Manufacturers are also responsible for the safety of their products, the truthfulness of their label claims and responsible to list dietary supplement ingredients including the amounts accurately on product's label.

FDA responsibilities are after dietary supplements enter marketplace, to monitor the safety and to make sure that the information on labels and packages insert are accurate and claims made for these products are truthful and not misleading. The responsibility of Federal Trade Commission, is to regulate advertising of dietary supplements and to make sure, that all advertising information's are truthful and not misleading.

It is important to highlight that FDA has the authority to take an action if marketed dietary supplement poses a direct health threat to consumers. Their enforcements are only after dietary supplement was marketed and adverse health effects have already occurred.

Several independent organizations offer quality testing for marketed dietary supplements and allow to pass International standard analytical tests to display their seals of approval on marketed dietary supplements. These seals of approval provide assurance that marketed dietary supplements are properly manufactured, contains ingredients listed on the label, and does not contain harmful levels of contaminants. However, these seals of approval still does not guarantee that marketed dietary supplements are safe or effective.

Finally consumers of dietary supplements are responsible for their own safety by selecting supplements with reliable ingredients and information's, selecting supplements with only ingredients they only need, avoid supplements with more than one herbal ingredient, purchase supplements from retail stores not from the internet, consult the physician on the safety of a supplement before purchasing, stop using a supplement if experienced side effect, and inform their personal physician or FDA for any experienced side effect.

Conclusion

There are thousands of dietary supplements in the market and many are non-effective or even some might cause harm than good, as in the case of some herbal supplements. Since there are little known about the safety of dietary supplements, consumers should consult with their personal physician and purchase dietary supplements with reliable and safety ingredients.

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