

The comprehensive review on Nutraceuticals: Introduction, History, classification, formulations, growth and development.

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ABSTRACT:

Nutraceuticals are a class of natural products that have been widely used in a wide range of therapeutic areas such as cough and cold, antiarthritis, digestion, sleeping disorders and treatment of cancers, depression, diabetes, cholesterol, blood pressure and pain killers. They are often considered to be somewhere between food and pharmaceutical products due to their dynamic action in sustaining health and preventing diseases. In recent years, however, the food composition has been scientifically tested and verified as people are becoming more and more aware of health-related issues and how food can directly or indirectly be responsible for maintaining proper health. Due to dynamic action of the food, their popularity amongst general public and healthcare providers has increased over medicines. In the last 10 years, a huge growth has been observed in the awareness of nutraceuticals and their use as powerful therapeutic supplements. A current review comprehensively discussed the use of nutraceuticals in prevention and support therapy, followed by compiled literature on patents published on said topic. This paper highlights some of the key regulatory challenges associated with the manufacturing and marketing of supplements. These challenges highlight the need for consistent and comprehensive regulatory frameworks to ensure the safety, efficacy, and quality of these products. By addressing these challenges, regulators can help to promote responsible development and marketing and ensure that consumers have access to safe and effective products.

Keywords: Nutraceutical, functional food, dietary supplement, antioxidants, disease modifiers, herbal nutraceuticals, nutraceutical products, oxidative stress.

I. INTRODUCTION:

Nutraceutical products can be considered non-specific biological therapies used to promote general well-being, control symptoms, and prevent malignant processes. The term “nutraceutical”

combines the two words of “nutrient,” which is a nourishing food component, and “pharmaceutical,” which is a medical drug. The term “nutraceutical” was coined in 1989 by Stephen De Felice, founder and chairman of the Foundation for Innovation in Medicine, an American organization which encourages medical health research. He defined a nutraceutical as a “food, or parts of a food, that provide medical or health benefits, including the prevention and treatment of disease”.

Nutraceuticals, in contrast to pharmaceuticals, are substances, which usually have no patent protection. Both pharmaceutical and nutraceutical compounds might be used to cure or prevent diseases, but only pharmaceutical compounds have governmental sanction.

Some popular nutraceuticals include ginseng, Echinacea, green tea, glucosamine, omega-3, lutein, folic acid, and cod liver oil. Majority of the nutraceuticals possess multiple therapeutic properties.

In the literature, other terms such as phytochemicals, herbs, spices, botanical medicines, dietary supplements, and secondary metabolites can be found, which can be mistaken for nutraceuticals. In the case of dietary supplements, these are known as concentrated sources of nutrients or other substances with a physiological or nutritional effect to complement the diet.

In the pharmaceutical industry, it is mandatory to do clinical tests on animals or in vitro for the verification of a compound’s effects. On the contrary, in nutrition, there was no such method in the past for the verification of effects of foods in preventing or treating diseases. In recent years, however, the food composition has been scientifically tested and verified as people are becoming more and more aware of health-related issues and how food can directly or indirectly be responsible for maintaining proper health and preventing diseases.

Nutraceuticals provide their benefits in a wide range of therapeutic areas such as cough and cold, anti-arthritis, digestion, sleeping disorders and treatment of cancers, depression, diabetes,

cholesterol, blood pressure and pain killers. The research and development sectors for nutraceuticals are working at their peaks to discover how various nutraceuticals can prove to be of significance in the pharmaceutical industry. Scientific needs for nutraceuticals demand standardization of the constituents and cautious development of protocols and implement clinical studies which will form the foundation for consumer health and impact on nutraceutical companies.

In the last 10 years, a huge growth has been observed in the awareness of nutraceuticals and their use as powerful therapeutic supplements. Nutraceutical medicine has now been accepted as a part of Complementary and Alternative Medicine (CAM) and, thus, it has been incorporated as a new branch of CAM.

Due to dynamic action of nutraceuticals (nutritional and medicinal action), their popularity amongst general public and healthcare providers has increased over medicines. A current review comprehensively discusses the use of nutraceuticals in preventive and support therapy, followed by compiled literature on patents published on said topic.

History:

Nutraceuticals, a type of food substance that helps to maintain health and prevent illness. The term nutraceuticals were introduced in 1989 by American medical doctor Stephen L. DeFeli. His concept of Nutraceuticals went back as far as 3000 years ago. Hippocrates (460–377 B.C) stated 'let food be thy medicine and medicine be thy food'. In the early 1900s the United States of America food manufacturers started adding small quantities of iodine to salt to prevent goiter. The term nutraceuticals were coined in 1989 by Stephen DeFelice who was the Chairman and Founder of the Foundation for Innovation in Medicine, Cranford, New Jersey. According to De Felice, nutraceutical can be said to be "a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease." However, functional food, dietary supplement, antioxidants, disease modifiers, herbal nutraceuticals, nutraceutical products, oxidative stress.

However, the term nutraceutical as commonly used in marketing has no regulatory definition. In England, Japan and other countries, nutraceuticals are already becoming part of the dietary landscape. Diet was first considered by Germany, France and the United Kingdom as a

more important factor than exercise or hereditary factors in achieving good health. Canada defined them as 'products of foods but sold in pills, powders, (potions) and other medicinal forms not normally associated with food'. In India, nutraceuticals are seen as the food components made from herbal or botanical raw materials, which are used for preventing or treating different types of chronic and acute maladies.

Nowadays, nutraceuticals are one of the most rapidly growing segments of the industry with an expected compound annual growth rate (CAGR) of 7.5% (Healthcare Packaging). The global nutraceutical market is estimated to increase from \$241 billion market in 2019 to \$373 billion in 2025 (Healthcare Packaging). The definite use of nutraceuticals has been to achieve desirable therapeutic outcomes with reduced side effects. Herbal Nutraceuticals are powerful instruments in sustaining health and act contrary to nutritionally induced acute and chronic diseases by promoting optimal health, longevity and quality of life.

Classification:

Nutraceuticals or functional foods can be classified on the basis of their sources: Natural or traditional and unnatural or non-traditional.

1. On the basis of natural source, it can be classified as the products obtained from plants, animals, minerals, or microbial sources. Can be referred to as Traditional Nutraceuticals.
2. Nutraceuticals as prepared via biotechnology: this classification can be referred to as Non-Traditional Nutraceuticals.

A) Traditional Nutraceuticals

They are natural products with no changes to the food. They contain numerous natural components that convey benefits beyond basic nutrition, like omega-3 fatty acids in salmon, saponins in soy or lycopene in tomatoes.

The traditional nutraceuticals can be divided on the basis of:

1. Chemical Constituents.
 1. Nutrients.
 2. Herbals.
 3. Phytochemicals.
2. Nutraceutical Enzymes.
 1. Chemical Constituents.
 3. Probiotic Microorganism

Nutrients:The nutrients include amino acids, fatty acids, minerals and vitamins with recognized nutritional functions. Most foods contain vitamins that aid in curing diseases like stroke, cataracts, osteoporosis and heart diseases. Minerals found in plants, animals and dairy products are useful in osteoporosis, anemia and in building strong bones, teeth, muscles, and improving nerve impulses and heart rhythm. Foods that contain fatty acids like omega-3 PUFAs are potent regulators of the inflammatory processes, maintenance of brain function and reduction in cholesterol deposition.

Herbals:Herbal nutraceuticals help to improve health and avert chronic diseases. Most of these are analgesic, anti-inflammatory, astringent, antipyretic and antiarthritic. Some of the herbals contain flavonoids like apiol, psoralen that are diuretic, carminative and antipyretic. Peppermint (*Mentha Piperita*) contains menthol as an active component that help cure cold and Some of the plants contain tannin which is claimed to aid in the management of depression, cold, stress, cough, hypertension and asthma while proanthocyanidin found in some herbals are useful in the treatment or prevention of cancer, ulcers and urinary tract infections.

Phytochemicals:Phytochemicals are plant nutrients with particular biological activities that promote human health. They are also referred to as Phytonutrients. They work by serving as substrate for biochemical reactions, cofactors or inhibitors of enzymatic reactions, absorbents that bind to and eradicate unwanted constituents in the intestine and improve the absorption and/or stability of indispensable nutrients among others.

Nutraceutical Enzymes:These are enzymes that are derived from plant, animal and microbial sources. Enzymes are an essential part of life, without which our bodies would cease to function optimally. Medical conditions such as blood sugar disorders, digestive problems and obesity have their symptoms eliminated by enzyme supplements in the diet.

Probiotic Microorganisms:Probiotics mean ‘for life’. They are defined as live microorganisms, which when consumed in tolerable amounts, confer a health effect on the host. These microorganisms are responsive bacteria that promote healthy digestion and absorption of some nutrients. They most importantly act to mob out pathogens, like yeasts and other bacteria and viruses that may

cause disease and develop a communally advantageous symbiosis with the human gastrointestinal tract. They possess an antimicrobial effect through altering the microflora, averting adhesion of pathogens to the intestinal epithelium, competing for nutrients necessary for pathogen survival, producing an antitoxin effect and retrogressing some of the consequences of infection on the intestinal epithelium, such as secretory changes and neutrophil migration. For instance, probiotics can cure lactose intolerance by enhancing the production of a specific enzyme (β -galactosidase) that can hydrolyze the offending lactose into its component sugar.

B) Non-Traditional Nutraceuticals:These are the artificial foods developed by biotechnology. The bioactive components in food samples are engineered to produce products for human-wellness. They can be grouped into fortified nutraceuticals and recombinant nutraceuticals.

Fortified Nutraceuticals:These are nutraceuticals from agrarian breeding or added nutrients and/or ingredients. Examples include cereals with added vitamins or minerals, milk fortified with cholecalciferol used in vitamin D deficiency, us with added folic acid, prebiotic and probiotic fortified milk with *Bifidobacterium Lactis* HN019 used in diarrhea, respiratory infections and severe illnesses, in children and orange juice fortified with calcium.

Recombinant Nutraceutical:Recombinant nutraceuticals include the making of probiotics and the extraction of bioactive components by enzyme/fermentation technologies as well as genetic engineering technology. Also, energy-providing foods, such as bread, alcohol, fermented starch, yogurt, cheese, vinegar, and others are produced using modern biotechnology. Examples include cows with lactoferrin deficiency engineered with recombinant human lactoferrin (rhLf) to be able to solve the lactoferrin deficiency.

C) In order to distinguish between the wide varieties of products there are multiple different types of products that fall under the category of nutraceuticals:

1. Dietary Supplements:A dietary supplement is a product that contains nutrients derived from food products that are in concentrated liquid or capsule form. Dietary supplements include - vitamins,

minerals, coenzyme Q, carnitine, etc. The Dietary Supplementation Health Education Act (DSHEA) formally defined “dietary supplement” using several criteria. A dietary supplement:

1. Is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herbal or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract or combinations for these ingredients.
2. Is intended for indigestion in pill, capsule, tablet or liquid form.
3. Is not represented for use as a conventional food or as the sole item of meal /diet.
4. Is labeled as a “dietary supplement.”
5. Includes products such as an approved new drug, certified antibiotic or licensed biologic that was marketed as a dietary supplement or food before approval, certification or license (unless the Secretary of Health and Human Services waives this provision)

1. Functional Foods:

Functional foods are designed to allow eating enriched food close to their natural state, rather than by taking dietary supplements manufactured in liquid or capsule form. Sometimes, additional complementary nutrients are added, such as vitamin D to milk (E.g. Oats, barn, psyllium and lignin’s for heart disease and colon cancer Prebiotics - oligofructose for control of intestinal flora, Canola oil with lowered triglycerides for cholesterol reduction, etc.)

2. Medical Foods

Medical foods are foods that are specially formulated and intended for the dietary management of a disease that has distinctive nutritional needs that cannot be met by normal diet alone. Medical foods aren’t available as an over-the-counter product to consumers. The FDA considers medical foods to be “formulated to be consumed or administered internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, on the basis of recognised scientific principles, are established by medical evaluation. “Medical foods can be ingested through the mouth or through tube feeding. Medical foods closely monitored by medical supervision.

D) The Food Sources Used As Nutraceuticals Are All Natural And Can Be Categorized As:

1. Dietary Fibre
2. Probiotics
3. Prebiotics
4. Polyunsaturated fatty acids
5. Antioxidant vitamin
6. Polyphenols
7. Spices

1. Dietary Fiber

Dietary fiber (DF) consists of non-digestible carbohydrates and lignins that are intrinsic and intact in plants. Functional fiber (FF) consists of isolated, non-digestible carbohydrates that have beneficial physiological effects in humans. Total fiber is the sum of dietary and functional fiber. These definitions broaden the category and allow resistant starches,

Oligosaccharides and other non-digestible carbohydrates to be classified as functional fibers. The adequate intake for fiber defined by the Dietary Reference Intake (DRI) is 38 grams/day for adult men and 25 grams/day for adult women. There was insufficient evidence to set a tolerable upper intake level for dietary or functional fiber. Probiotics are live bacteria and yeasts that are good for your health, especially your digestive system. We usually think of bacteria as something that causes diseases.

But your body is full of bacteria, both good and bad. Probiotics are often called "good" or "helpful" bacteria because they help keep your gut healthy. Probiotics are naturally found in your body. You can also find them in some foods and supplements. It's only been since about the mid-1990s that people have wanted to know more about probiotics and their health benefits. Doctors often suggest them to help with digestive problems. And because of their newfound fame, you can find them in everything from yogurt to chocolate.

Lactobacillus- This may be the most common probiotic. It's the one you'll find in yogurt and other fermented foods. Different strains can help with diarrhea and may help with people who can't digest lactose, the sugar in milk.

3. **Bifidobacterium**-You can also find it in some dairy products. It may help ease the symptoms of irritable bowel syndrome (IBS) and some other conditions.

Probiotics help move food through your gut. Researchers are still trying to figure out which are

best for certain health problems. Some common conditions they treat are:

- Irritable bowel syndrome
- Inflammatory bowel disease (IBD)
- Infectious diarrhea (caused by viruses, bacteria, or parasites)
- Antibiotic-related diarrhea. There is also some research to show they help with problems in other parts of your body. For example, some people say they have helped with:
- Skin conditions, like eczema
- Urinary and vaginal health
- Preventing allergies and colds
- Oral health

Prebiotics

Prebiotics are substances that induce the growth or activity of microorganisms (e.g., bacteria and fungi) that contribute to the well-being of their host. The most common example is in the gastrointestinal tract, where prebiotics can alter the composition of organisms in the gut microbiome. However, in principle it is a more general term that can refer to other areas of the body as well. For example, certain hand moisturizers have been proposed to act like prebiotics to improve the activity or composition of skin microbiota

In diet, prebiotics are typically non-digestible, fiber compounds that pass undigested through the upper part of the gastrointestinal tract and stimulate the growth or activity of advantageous bacteria that colonize the large bowel by acting as substrate for them (Gibson GR et al., 1991). As a functional food component, prebiotics, like probiotics, are conceptually intermediate between foods and drugs. Depending on the jurisdiction, they typically receive an intermediate level of regulatory scrutiny, in particular of the health claims made concerning them. Although all prebiotics are fiber, not all fiber is prebiotic. Classification of a food ingredient as a prebiotic requires scientific demonstration that the ingredient (Jacob RA, 1995)

- Resists gastric acidity, hydrolysis by mammalian enzymes, and absorption in the upper gastrointestinal tract;
- Is fermented by the intestinal microflora;
- Selectively stimulates the growth and/or activity of intestinal bacteria potentially associated with health and well-being.

Health benefit of prebiotics

The health outcome data for prebiotic intake is substantially more limited than for dietary fiber.

However, it has been suggested that prebiotic intake may:

- Reduce the prevalence and duration of infectious and antibiotic-associated diarrhea;
- Reduce the inflammation and symptoms associated with inflammatory bowel disease;
- Exert protective effects to prevent colon cancer;
- Enhance the bioavailability and uptake of minerals, including calcium, magnesium, and possibly iron;
- Lower some risk factors for cardiovascular disease; and
- Promote satiety and weight loss and prevent obesity

4. Polyunsaturated Fatty Acids

The group of poly-unsaturated fatty acids (PUFAs) is divided into two groups: omega-3 (n-3) and omega-6 (n-6) polyunsaturated fatty acids (PUFA), differing in the position where the first double C-bound is located. Two PUFAs are called essential fatty acids since they cannot be synthesized in the human body and are vital for physiological integrity. Therefore, they must be obtained from the diet. One is linoleic acid (LA) and belongs to the n-6 family. The other one is α -linolenic acid (LNA) belonging to the n-3 family. These essential parent compounds can be converted in the human body to long chain (LC) fatty acids but humans cannot interconvert n-3 and n-6 fatty acids.

5. Antioxidants

Damage to cells caused by free radicals is believed to play a central role in the aging process and in disease progression. Antioxidants are our first line of defense against free radical damage, and are critical for maintaining optimum health and wellbeing. Oxygen is a highly reactive atom that is capable of becoming part of potentially damaging molecules commonly called "free radicals." Free radicals are capable of attacking the healthy cells of the body, causing them to lose their structure and function. Antioxidants are capable of stabilizing, or deactivating, free radicals before they attack cells. Antioxidants are absolutely critical for maintaining optimal cellular and systemic health and wellbeing. Humans have evolved a highly sophisticated and complex antioxidant protection system. It involves a variety of components, both endogenous and exogenous in origin, that function interactively

and synergistically to neutralize free radicals. These components include:

- Nutrient-derived antioxidants like ascorbic acid (vitamin C), tocopherols and tocotrienols (vitamin E), carotenoids, and other low molecular weight compounds such as glutathione and lipoic Acid.
- Antioxidant enzymes, such as superoxide dismutase, glutathione peroxidase, and glutathione reductase, which catalyze free radical quenching reactions.
- Metal binding proteins, such as ferritin, lactoferrin, albumin, and ceruloplasmin that sequester free iron and copper ions that are capable of catalyzing oxidative reactions.
- Numerous other antioxidant phytonutrients Present in a wide variety of plant foods.

Additional physiological antioxidants are –

Endogenous Antioxidants

1. Bilirubin
2. Thiols, e.g., glutathione, lipoic acid, N-acetyl cysteine
3. NADPH and NADH
4. Ubiquinone (coenzyme Q10)
5. Uric acid
6. Enzymes

6. Dietary Antioxidant:

- a. Vitamin C
- b. Vitamin E
- c. Beta carotene and other carotenoids and oxy carotenoids such as lycopene and lutein
- d. Polyphenols, e.g., flavonoids, flavones and flavanols Proanthocyanins

7. Metal Binding Proteins:

- a. Albumin (copper)
- b. Ceruloplasmin (copper)
- c. Metallothionein (copper)
- d. Ferritin (iron)
- e. Myoglobin (iron)
- f. Transferrin (iron)

Challenges And Opportunities:

Nutraceuticals and nutrition supplements are collectively referred to as “dietary supplements,” intended to be taken orally. The use of supplements is suggested to (but may not claim to) diagnose, cure, mitigate, treat, or prevent diseases. Often, background information suggests that they are intended to affect the structure or function of the body. However, they do not undergo premarket approval. The common reasons for using dietary supplements are to improve

conditions such as overall health and disease prevention, performance (athletics, sports, sex, etc.) and appearance (weight loss, sex appeal). These are often perceived as “safe” and less likely to have side effects. The scientific research on nutraceuticals and nutrition supplements is frequently misinterpreted or overstretched for commercial interests because of high consumer demands. The manufacturing and marketing of supplements are full of challenges. Several challenges associated with the development of nutraceuticals are often ignored because of a lack of authoritative control. These challenges include identification of the authentic source of raw materials, purity of the compound, presence of other active compounds, quality, lack of experimental evidence, false advertising, contamination with heavy metals, and interactions between supplements and drugs. For example, a common herb “ginseng” has several varieties such as California ginseng, wild ginseng, prickly ginseng, Pacific ginseng, Malaysian ginseng, Indian ginseng, Peruvian ginseng, Southern ginseng, Brazilian ginseng, and wild-red ginseng. All of these are sold as ginseng, but none of these belongs to the genus *Panax*, which contains real ginseng including Korean ginseng (*P. ginseng*), South China ginseng (*P. notoginseng*) and American ginseng (*P. quinquefolius*). Some varieties of star anise have several hundred-fold anisatin, a neurotoxin, that the authentic star anise (*Illicium verum*) has the supplements that are not prepared under strict GMP conditions may have unintentional contamination, including microbes (pathogens/nonpathogens), pesticides, mycotoxin (aflatoxin), heavy metals (seaweeds), zinc (cadmium), and calcium (lead). In addition, some supplements such as those commonly used for weight loss, bodybuilding, and sex enhancement are spiked with prohibited drugs to improve efficacy. Some manufacturers also try to use a closely related herb, which may or may not have the active ingredients. For example, goldenseal (*Hydrastis canadensis*), used for berberine/hydrastine content, is often substituted with goldthread (*Coptis chinensis*) or Oregon grape (*Mahonia aquifolium*), which may have low or no berberine/hydrastine.

Besides, maintaining the quality of nutraceuticals is another challenge, as phytochemistry is inherently variable due to seasonal and geographical variations. It is challenging to measure and maintain consistency in finished products and limit undesirable

constituents. Interaction of herbal supplements with medicinal drugs is also a big concern. For example, St. John's wort (*Hypericum perforatum*) is used as an effective antidepressant, but it also activates several cytochrome P450 isoenzymes, which make a large number of medicinal drugs ineffective. Among all the major concerns for using the nutraceuticals is the lack of scientific evidence. Some are never tested under properly controlled experimental conditions, and unlike pharmaceuticals, most nutraceuticals do not undergo "randomized controlled clinical studies."

Formulations:

Tablets:

A solid dosage form of dry ingredients compressed into a pill. Tablets can be any shape and size to make it easy for swallowing.

Tablets may contain active ingredients blended uniformly throughout or separated into different layers within the tablet.

At Nugen Research, we make certain that all of your tablets are made with the best ingredients to provide the highest quality. We also offer coated tablets that can be packaged into bottles, multi-pack sachets, or blister packs according to your requirements.



Fig no. 01 Tablets

Chewable Tablets:

A tablet that is intended to be chewed before swallowing. Chewable tablets are made using lower compression forces to allow the tablet to dissolve in the mouth as it is chewed. Chewable tablets are convenient for individuals who have difficulty swallowing pills.



Fig no. 02 Chewable Tablets

Capsules:

A solid dosage form consisting of a shell and a filling. The shell is composed of two halves that fit together that are sometimes sealed with a band. Capsule shells may be made from gelatin, starch, or cellulose, or other suitable materials and filled with dry or liquid ingredients.

Capsules are the standard and one of the most common forms of dosages in the dietary supplement industries.



Fig no. 03 Capsules

Soft Gel:

A softgel is a type of soft capsule filled with liquid ingredients. The shell consists of gelatin, water, and a plasticizer such as glycerin or sorbitol. Softgel can be made into various shapes and sizes to make it easy for swallowing.



Fig no. 04 Soft Gel

Powder:

Powders may be coarse or fine and are often agglomerated to enhance dissolution when stirred into a liquid. Powders are used when large serving sizes are required.

Nugen Research has the resources, equipment and experience necessary to formulate and mix all sizes of powder products. Our modern mixing and packaging equipment give Nugen Research the ability to create homogenous and consistent powder products whether in jugs, pouches or stick packs or other types of powder packaging that suit your powder solutions.



Fig no. 05 Powder

Liquid:

Active ingredients can be dissolved or blended into any liquid approved for human consumption. Limitations are placed on the volume of liquid per serving to be classified as a dietary supplement and not a beverage.



Fig no. 06 Liquid

Gummy:

A gummy is a gelatin-based soft chewable candy containing active ingredients. Gummies are convenient for individuals who have difficulty swallowing pills.



Fig no. 07 Gummy

Lozenge:

A hard candy-like dosage form that is intended to dissolve or disintegrate slowly in the mouth.



Fig no. 08 Lozenge

Labeling Requirements:

Labelling Provisions under FSSAI. The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food)

Regulations, 2016 provides for the following labeling requirements for nutraceuticals:

- The labeling or presentation must not claim that the nutraceutical product has the property of preventing, curing or treating a human disease. It must not even refer to any such properties.
- Only when the statement made by the brand regarding the structure or function or the general well-being of the body is supported by scientific evidence, the food authority will allow such a statement.

Every package of food containing nutraceuticals shall carry the following information on the label:

- The word 'NUTRACEUTICAL'
- The common name of the nutraceutical
- A declaration about the amount of each nutraceutical ingredient in the product that has either a nutritional or physiological value o When nutrients are added it must be mentioned along with its quantity expressed in terms of percentage of the recommended daily allowances as specified by the Indian Council of Medical Research (ICMR) even if the nutrient is in addition to a nutraceutical, and shall bear an advisory warning not to exceed the stated recommended daily usage'
- An advisory warning for 'RECOMMENDED USAGE'
- An advisory warning 'NOT FOR MEDICINAL USE' should be prominently written
- An advisory warning in case of possible danger from excessive consumption
- An advisory warning or any other warning or precaution to be taken while consuming, known side effects, contraindications, and product-drug interactions, as applicable
- A statement that the product is required to be stored out of reach of children

Labeling Provisions Under The Legal Metrology Law-

1. The Legal Metrology Packaged Commodities Rules, 2011 provides for various guidelines for labeling in case of packaged goods. Nutraceuticals being a packaged commodity.
2. The common or generic names of the commodity must be mentioned on the label and if the commodity has more than one product then the number of each product must be mentioned
3. The net quantity or the number of the commodity must be mentioned
4. Information on best before or use by i.e. Expiry date must be mentioned if the product may become unfit for human consumption
5. The retail sale price of the package
6. Where the size of the packages is an important feature then the dimensions of the commodity must be mentioned
7. It must be ensured that each package bears the name, address, telephone number, E-mail address of the person or office to be contacted in case of consumer complaints

8. it's not permissible to affix individual stickers on the package for making any declaration or altering it under these rules.
9. Where the commodity consists of a number of components packed in units to be sold as a single commodity the declarations must be made on the main package or such declaration must be given on individual packages and intimation of the same shall be given on the main package.

Apart from the above-mentioned declarations, there are certain quantity declarations Rules covering weight, volume, length, & number. The declarations must be made in the right manner and various rules have been laid down as to how and where one should make the declarations depending on the shape and size of the product. Every declaration must be legible and prominent and must be made on the principal display panel. The mandatory declaration on the packaging of products can be accessed here
Penalty for non-compliance with the Rules may extend to IN 25000 for first offense, Rs 50000 for second offense and for subsequent offense the fine would not be less than Rs 50000 and may extend to Rs 1.00.000 or imprisonment which may extend to one year or both.

Regulatory Challenges:

1. Nutraceuticals face several regulatory challenges around the world, as they are often considered to be somewhere between food and pharmaceutical products. Here are some of the key regulatory challenges for nutraceuticals:
2. Lack of harmonized regulations: Nutraceuticals are regulated differently in different countries, and there is a lack of harmonization in regulatory requirements. This can make it difficult for companies to navigate the regulatory landscape and can result in inconsistencies in product quality and safety
3. Safety concerns: While many nutraceuticals are generally considered safe, there have been instances of adverse reactions and even deaths associated with their use. The lack of pre-market safety evaluations and monitoring can make it difficult to ensure the safety of these products
4. Labeling and marketing claims: Nutraceuticals often make health claims on their packaging and in their marketing materials, which can be difficult to substantiate. Regulators around the

world are increasingly cracking down on unsubstantiated health claims, which can make it challenging for companies to market their products effectively

5. **Quality control:** Ensuring the quality of nutraceutical products can be challenging, as many of the ingredients are derived from natural sources and may vary in potency and pungency. This can make it difficult to establish consistent quality standards for these products
6. **Intellectual property:** The development and commercialization of nutraceuticals can be complicated by intellectual property issues, including patents and trademarks. This can make it difficult for smaller companies to compete with larger players in the industry.
7. **Lack of clinical trials:** While some nutraceuticals have been studied in clinical trials, many have not undergone rigorous scientific testing. This can make it difficult to establish the efficacy of these products and can also hinder their acceptance by the medical community.

These regulatory challenges for nutraceuticals highlight the need for consistent and comprehensive regulatory frameworks to ensure the safety, efficacy, and quality of these products. By addressing these challenges, regulators can help to promote the responsible development and marketing of nutraceuticals and ensure that consumers have access to safe and effective products.

Regulation Of Nutraceutical In India:

In India, nutritional supplements are referred to as "foods for specific dietary uses." The FSSA defines various categories of food items, including foods for specific dietary uses, functional foods, nutraceuticals, and health supplements (HS).

The Food Safety and Standards Act of 2006 established the FSSAI to regulate the production, storage, distribution, sale, and import of food items, including nutraceuticals and nutritional supplements. This act replaced several previous laws, such as the Prevention of Food Adulteration Act of 1954 and the Vegetable Oil Products Order of 1955. The FSSAI is responsible for setting standards for food items based on scientific principles to ensure that safe and wholesome food is available for human consumption.

Indian Regulatory Process:

The Food Safety and Standards Authority of India is largely responsible for overseeing the regulation procedure for nutraceuticals in India (FSSAI). The FSSAI controls the country's production, import, sale, and distribution of dietary supplements. A description of the regulatory procedure:

1. FSSAI License
2. Product categorization
3. Requirements for Labeling
4. Assurance of quality and safety
5. Commercials and Claims
6. Inspections and Compliance

TABLE: Classification of nutraceutical products for each country based on the governmental agency and the regulatory guidelines.

Country	Regulatory body	Act
Australia	Therapeutic Administration (TGA)	New south Wales Government - Food regulation, 2010
Canada	Health Canada (HC)	Natural Health Product Directorate (NHPD), 2003
Japan	Ministry of Health, Labour, and Welfare (MHLW) consumer affairs agency (CA) for supplements	Food with Nutrient function claim (FNFC) 2005
India	Food safety and Standards Act (FSSA)	Food Safety and Standard authority of India (FSSAI), 2010
United state	Food and drug Administration (FDA)	Food safety Modernization Act (FSMA), 2011

Schedules for Food and Nutraceuticals:

The Indian Food Authority has released a draught of the Food Safety and Standards (HS, Nutraceuticals, food for special dietary use (FSDU), food for special medical purpose (FSMP), and prebiotic and probiotic food [Pre-Pro]) Regulations, 2022. (FSSAI). According to the FSSAI, these regulations will benefit the nutraceuticals industry by offering clear standards and enabling field functionaries to more effectively ensure compliance on the ground. Food items covered by these standards are carefully prepared or processed for particular dietary or nutritional needs, and they should be distinct from foods meant for everyday consumption

II. CONCLUSION:

Due to dynamic action of the food, their popularity amongst general public and healthcare providers has increased over medicines. These challenges highlight the need for consistent and comprehensive regulatory frameworks to ensure the safety, efficacy, and quality of these products.

Acknowledgment:

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