



(REVIEW ARTICLE)



## Nutraceuticals: An alternative to pharmaceuticals

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### Abstract

The study is aimed to highlights the different aspects of nutraceuticals including market trends, difficulties, and the processing methods used to harness natural resources. A very broad "nutraceutical" rise has been caused by the nutraceuticals' reach for healthcare management of chronic disorders. The majority of settings had a negligible impact on inadequate eating and lifestyle choices. Research on nutraceuticals is very important and reasonably priced. The healthcare and pharmaceutical industries are facing difficulties as a result of its financial system. It has been found that nutraceuticals contribute to the prevention of infection and cancer and have a positive effect on immune system and cardiovascular health. Based on their composition and mode of action, nutraceuticals are categorized into classes. The many kinds of nutraceuticals and their potential therapeutic effects in illness, such as their anti-inflammatory, anti-cancer, antioxidant, and anti-lipid properties, will be discussed in this review. Additionally Over the last fifty years, lifestyles have been significantly impacted by urbanization, the rate of industrialization, and rapid change. which resulted in the formation of a junk food eating habit. The ability to eat healthily is impacted by these practices, which gradually reduce the quantity and quality of nutrients consumed. Dementia, starvation, and degenerative diseases are becoming more common as a result of the population's changed eating habits. In recent years, people's worries about their health and ability to receive healthcare have grown. Nutraceuticals are essential for boosting immunity without compromising the body's natural defenses. Nutraceuticals are present in active foods, designer meals, medical diets, dietary supplements, and other diet regimens that offer additional health benefits. Nutrient-rich foods help with a number of bodily functions, including the prevention and treatment of diseases. The medicinal plant offers a range of phytochemical qualities to address different medical issues.

**Keywords:** Nutraceuticals; FSSAI; Health supplements; Dietary Supplement; Conventional

### 1. Introduction

Customers' increasing demand for nutraceutical products has resulted in a global nutraceutical exploitation. This is a result of the escalating health care costs linked to conventional medicines, the frequent side effects of pharmaceutical products, and the widespread belief that compounds that resemble food are safe in comparison to conventional medications. Stephen Defelice, MD, is the founder and chairman of the Foundation for Innovation in Medicine (FIM) since 1989. He is credited with coining the term "nutraceutical," which he defined as any substance that can be consumed or used as a food ingredient that has therapeutic or health benefits, including the potential to prevent or treat illness [1].[2].[3].

Nutraceuticals are becoming more and more popular as a result of their use in healthcare to treat chronic illnesses [4]. Because of their seeming safety and possible health and nutritional advantages, nutraceuticals and functional foods attracted a lot of attention. Given consumer interest in these goods, the functional food and nutraceutical industries are well-positioned to benefit [5].[6]. Many diseases, including allergies, Alzheimer's disease, cardiovascular and ocular

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disorders, cancer, obesity, diabetes, and Parkinson's disease, as well as the control of immune system function and inflammation, may be prevented or treated with nutraceuticals, according to recent studies [7].[8].

Worldwide, the use of nutraceuticals is growing rapidly and is constantly being developed [9]. These include components, such as B vitamins and low-calorie sweets, that have been demonstrated to be beneficial to human health. The future nutraceutical program will focus on specific diagnostic models, human clinical research, and comprehension in order to better understand the precise mechanism of action that is beneficial in the prevention and treatment of diseases. Nutraceuticals have been demonstrated to support health and strengthen immunity when taken as prescribed [10].[11].

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## 2. Regulation and guidelines

In essence, nutraceuticals are nutritional elements that are essential to the growth and upkeep of the body's normal processes, which keeps people healthy. An further significant driver of the nutraceutical sector is the present global population and trends. Nutraceuticals are foods that include additional natural or herbal foods, fiber, probiotics, polyunsaturated fatty acids, antioxidants, and prebiotics. Historically, COVID-19 and diabetes mellitus have been among the most serious health problems that nutraceuticals have assisted in managing. We are entering a time of health and medicine, and the food business as a whole has turned its attention to research.

### 2.1. Laws Governing Nutraceuticals

Nutraceuticals are governed by a number of laws with different names, depending on the country. Nutraceuticals are different from dietary supplements depending on the region, and in certain countries they are considered food. Generally speaking, a dietary supplement is an oral drug composed of a dietary component that is intended to be an addition to a diet. Worldwide, a variety of definitions and terms are used to indicate what a nutraceutical is like. Dietary supplements are referred to as Natural Health Products in the USA, Complementary medicines in Australia, Foods for Special Dietary Use in India and Food Supplements in the European Union [12].[13].

While the United States, the United Kingdom, and Europe have simplified their regulations to make them more favorable for the development of nutraceutical products, the Indian industry and regulatory landscape are still relatively new, but they have a lot of potential to grow and be able to compete with other international organizations. India's nutraceuticals industry is expanding quickly, and the country has taken a number of steps to position itself as a major player in the field going forward.

When it comes to figuring out if a product belongs in the food or medication category, the National Pharmaceutical Regulatory Agency (NPRA) and the Food Safety and Quality Division (FSQD) are the two Ministry departments that are highlighted [14].[15].

### 2.2. Key information about nutraceuticals in India

There aren't many businesses in India that solely focus on producing nutraceutical items; instead, the majority of the market is controlled by Fast Moving Consumer Goods (FMCG) and pharmaceutical corporations. The Indian market for nutraceuticals is one of the fastest-growing because of rising health consciousness, rising incomes, and rising living standards [16]. Despite the economic slump and growing rates of inflation, the Indian nutraceuticals sector is continuing to grow. Numerous data suggest that nutraceuticals have enormous growth potential in India. The entire nutraceutical market in India is expanding at a rate of 21% annually, according to a report published by Netscribes India Pvt. Ltd.

It is currently worth INR 44 billion, but in four years it can be worth INR 95 billion or more [16]. Frost and Sullivan projected a growth of 2,731 million at a CAGR of 13.0 percent in a different recent report [17].

In India, the main factors propelling the rise of nutraceuticals are: Population Aging; Rising Death Rate from Heart Disease, Diabetes, and Obesity Annual Disposable Income; Internet Users; Healthcare Expenditure; National Urban Population's Spending Patterns.

**Indian Requirements for Regulation Product Evaluation:** Analysis of all additives and active substances. Steps in the process of evaluating the product include: The creation of document extracts Sample collection (conducted in front of witnesses) Sample delivery to the relevant authorities (various procedures for individual and large packages) • Analysis of food Should the study be finished before the deadline, the assigned officer will devise an additional action plan. • Proceedings for adjudication (holding inquiry, appeals process, hearing, etc.) 2. Licensing: Almost four or five licenses,

which cover the following, may be needed in order to have a product registered in India: Licenses related to imports, manufacturing, marketing, and Before launching these items in India, it is necessary to obtain additional regulatory certifications and licenses at the state and national levels. 3. Health and label claims: A "health claim" is any assertion, recommendation, or deduction that a food or a component there of has something to do with health. This covers the following: India-specific labeling and packaging specifications The way the consignment is packaged, its substance, and its marketing strategy Sample material and declaration are required for registration. Label content and claim are also necessary. Structure - function assertion in Nutraceuticals are defined by USFDA regulations as dietary supplements, and the regulations were first published in 1994 Dietary supplements and their components are subject to FDA regulation under the Dietary Supplement Health and Education Act (DSHEA), which has its own set of regulations [13].

The FDA was given the authority to control and keep an eye on the safety of food, medicine, and cosmetic items by the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, the two primary product categories were food items and medicine goods. The regulatory frameworks for the two streams are distinct. Nutraceuticals must abide by all FFDCA regulations for conventional foods since they are governed as a food category. This occurs as a result of the 1994 DSHEA, which established a new class of goods known as dietary supplements [18].

The primary set of laws governing the nutraceutical sector was created in 1946 and is known as the Dietary Supplement Health and Education Act (DSHEA). The Food Safety and Standard Authority has also established regulations regarding food product standards, manufacturing, labeling, packaging, and licensing for food businesses. As of August 2011, the Food Safety and Standard Rule and Regulations are in force. This law will incentivize producers to conduct clinical research, create dependable protocols, and conduct product RandD. The Foreign Direct Investment Act, which was recently passed in 2012, offers new chances for foreign businesses to produce and market nutraceutical goods in India [19].

### **2.3. Food Standard Safety Act (FSSA)**

To combine and simplify the numerous laws governing foods, dietary supplements, and nutraceuticals, the Indian government approved the Food Safety and Standard Act in 2006. The establishment of the Food Safety and Standards Authority (FSSA) is mandated by the act. The Food Safety Authority's (FSSA) job is to provide guidelines and policies that allow food-related businesses to get licenses from local authorities. It also creates a system of checks and balances that includes product recall procedures, enforcements, and penalties [20]. The 2011 Food Safety guidelines and requirement Rules are now available, going into effect on May 5th. It is required by the FSS Act for food and nutritional facilities to register with the FSSAI. A system for online registration is offered for the import, export, and manufacturing of food and nutraceutical facilities. In the past, India had numerous rules governing nutraceuticals, and it was exceedingly challenging for the industry to comply with them all. In order to simplify and unify the various laws regulating foods, dietary supplements, and nutraceuticals, the Indian government passed the Food Safety and Standard Act in 2006.

The act stipulates that the Food Safety and Standards Authority (FSSA) must be established. The role of the Food Safety guidelines and requirement Rules Authority (FSSA) is to establish regulations and guidelines that enable enterprises involved in food to get licenses from regional authorities.

Additionally, it establishes a system of checks and balances including enforcements, penalties, and processes for product recalls [20]. The 2011 Food Safety guidelines and requirement Rules are currently accessible for manufacturers, and they will take effect on May 5. As a last point, the 12th report of a number of committees, including the standing committees of parliament on agriculture, was submitted in 2005 and underlined the necessity of an integrated law and a single regulatory agency. With the passage of the Indian Food Safety guidelines and requirement Bill 2005 into law, the Indian food processing industry was expected to be significantly impacted [21].

The Prevention of Food Adulteration Act, 1954; Fruit Products Order, 1955; Meat Food Products Order, 1973; Vegetable Oil Products (Control) Order, 1947; Edible Oils Packaging (Regulation) Order, 1988; Solvent Extracted Oil, De-Oiled Meal and Edible Flour (Control) Order, 1967; Milk and Milk Products Order, 1992, and other Central Acts were repealed after the Food Safety and Standards Act, 2006 went into effect. Another goal of the Act was to establish a single point of contact for all matters relating to Food Safety guidelines and requirement Rules by moving away from multi-level, multi-departmental control and toward a single line of command [22].

### **2.4. Licensing /Registration System under FSSAI**

Obtaining a license or registration granted by the local authorities is mandatory for all individuals involved in the food industry. Temporary both owners are not required to have a license, but they must register their companies with the

panchayat or local government. Prior to launching these products in India, import licenses, production licenses, and other regulatory clearances and licenses at the national level must be obtained. Given that there are several variables that affect the actual process, the FSSAI claims to streamline the licensing and registration procedures for nutraceuticals.

Depending on the actual condition of the product, several licenses (almost four to five) may be needed for product registration in India. These licenses include: Whether the business wishes to offer the medicine in bulk or in final formulation Whether the business imports bulk commodities or finished products Whether India is involved in the goods that needs to be imported • particular label Will India be the source of the claims? • Does the business possess a packaging license? If a manufacturing license is needed; if a marketing license is needed; Along with registration application dossiers, food importers, exporters, and manufacturers must provide a number of documents to the relevant government agency [21].[22].

**Central Licensing System Registration for Manufacturing Facilities** The Food Safety Standard Authority of India has developed an online registration process for food facilities (production, export, and import). The State Authority/Regional Office of Food Safety and Standards of India must receive the online application within fifteen days of the date of submission. The application must be submitted together with the required payments and accompanying documentation. Various permits are needed for the registration of nutraceutical products in India, depending on the product's actual state.

The importer must also provide product dossiers and reveal a number of documents to the appropriate government official in order to be granted a license. The significance Permission to produce Authorization for promotional purposes State and federal regulatory clearances and licenses must be obtained in addition before these products are introduced in India.

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### 3. Stability

The growing consumer market share for wellness products has drawn attention to nutraceuticals, which have been gaining popularity recently.

This has led to increased attention being paid to the FDA-based rules, production, marketing, and substantiation of claims about nutraceuticals. Herbs, minerals, vitamins, medicinal foods, dietary supplements, and other items would all be considered nutraceuticals in a loose sense. Stability testing is important [23].[24]. The well-being of patients is ensured by stability testing of medicine quality.

In regards to the patients afflicted with illnesses, it guarantees the safety of pharmaceutical dosage forms. When a new product is being developed, stability studies at an early stage can offer a database that could be useful in choosing the right formulation to ascertain shelf life, container closure system, and storage conditions. Stability studies are necessary to determine the quality of a drug product that has been modified or repackaged. These studies evaluate the drug product's potency, purity, and physical attributes (like color, caking, hardness, phase separation, and re-suspendability) over the course of its specified shelf life. Stability testing of the dosage should be done in the final package system of in containers and closure in which the clinical trial is to be proposed. The testing parameters will vary with different dosage forms; stability studies should include testing of those attributes of the pharmaceutical product that are susceptible to change during storage and are likely to influence quality, safety and efficacy [25].

#### 3.1. Guidelines for stability testing

The regulatory authorities in several countries have incorporated requirements for manufacturers to disclose stability data in their medication rules in order to ensure that the best possible stable molecules and products are produced, disseminated, and given to patients. The primary objective was to harmonize testing protocols throughout manufacturers. These guidelines cover fundamental stability-related concerns, the stability data requirements for application dossiers, and the procedures for carrying them out. These guidelines were first published in the 1980s. Subsequently, these were harmonized, or made uniform, at the International Conference on Harmonization (ICH), which helped remove the obstacle to registering and marketing the products abroad. The European Commission, Japan, and the United States of America provided regulatory and industry input to form the ICH consortium. The World Health Organization (WHO) changed the guidelines in 1996 because the ICH guidelines only found substances and products, not the established products that were already in use in the WHO umbrella countries, and they failed to address the extreme climatic conditions found in many countries [26].[27]. Stability testing techniques can be divided into four categories based on the objectives and steps involved. These are: 1. Real-time stability testing 2. Quicker stability examination 3. Testing for stability of retained samples 4. Stress testing with cyclic temperatures [28].[29].

### 3.2. Labeling and Claims

Nutraceutical Labeling and Claims Labeling and strict regulations on formulae and branding are still unnecessary for the majority of items. The purpose of health claims on nutraceuticals is to tell consumers that they may lower the risk of certain diseases when taken in conjunction with a healthy diet. The FDA initially approved seven health claims in 1993 as part of the 1990 Nutrition Labelling and Education Act (NLEA). The FDA has authorized six more claims since 1993. A provision to hasten the process of establishing the scientific underpinning for health claims was included in the Food and Drug Administration Modernization Act of 1997 to assist consumers obtain this information more quickly.

In spite of the fact that food manufacturers may use health claims to promote their goods, leads to benefit consumers by providing information on heart-healthy eating practices that may help reduce the risk of cancer, heart disease, osteoporosis, high blood pressure, dental cavities, or specific birth defects. Health claims are distinct from structure/function assertions, which can also be seen on labels for common foods or dietary supplements. Claims related to structure and function do not cover illness risk reduction, in contrast to health claims. Moreover, the FDA does not allow or preapprove claims related to structure or function. As academic, scientific, and regulatory bodies are looking into how to develop the scientific foundation for claims (other claims), it is the manufacturer's responsibility to make sure that any structure/function claims it makes are true and not misleading by academic, scientific, and regulatory forums. The labels of foods and dietary supplements contain the following five categories of health-related statements: The existence of a specific nutrient at a given amount is indicated by nutrient-content claims. The influence of food ingredients on the body's typical structure or function is explained by assertions about structure and function. The health benefits of particular food groups are highlighted in dietary advice claims. Academic, scientific, and regulatory organizations are looking into how to establish the scientific foundation for claims (other than health claims) for nutraceutical functional components. When a manufacturer makes a structure/function claim, the firm is responsible for making sure the claim is accurate and not misleading. Food and nutritional supplement labels contain the following five categories of health-related statements:

- Claims about the nutrients present indicate the presence of a certain nutrient at a specific level. The impact of dietary components on the body's normal structure or function is explained by assertions about structure and function. Dietary guideline claims highlight the benefits of particular dietary groups for health.
- As acknowledged by the FDA and supported by evidence, qualified health claims indicate an increasing correlation between dietary components and the risk of illness.
- Health claims show a connection between dietary components and the chance of sickness or health condition, as verified by a significant body of credible scientific evidence, as approved by the FDA and supported by a significant body of scientific agreement [30].

### 3.3. Labelling Provisions under FSSAI

In FSSAI's Labeling Requirements Nutraceuticals must comply with the following labeling standards, under 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: A nutraceutical product's ability to prevent, cure, or treat a human disease cannot be stated on its label or in its presentation. It is not allowed to mention any of these attributes at all. The food authority will only approve a statement made by a brand about the contains nutraceuticals: "NUTRACEUTICAL" is the word. The nutraceutical's common name An explanation of how much of each nutraceutical ingredient—which has both physiological and nutritional value—there is in the product If nutrients are added, they must be disclosed along with their quantity, expressed as a percentage of the Indian Council of Medical Research's (ICMR) recommended daily allowances. This applies even if the nutrients are added in addition to nutraceuticals, and they must come with an advisory warning to "not exceed the stated recommended daily usage." · A "RECOMMENDED USAGE" alert warning It should be clearly stated, "NOT FOR MEDICINAL USE," in the advisory warning. A cautionary note regarding the potential risk of consuming too much An advise caution, or any other caution or advice to be followed when ingesting. A cautionary note regarding the potential risk of consuming too much Any pertinent cautions or warnings to be followed when taking, including known side effects, contraindications, and product-drug interactions a declaration stating that children must not have access to the goods when being stored Away [31].[32].[33].

### 3.4. Legal Metrology Law's Labeling Requirements

A number of labeling rules for packaged commodities are provided under the Legal Metrology Packaged Commodities Rules, 2011. Given that they are packaged goods, nutraceuticals have to follow these rules. If the product has many products, the number of each product must be stated on the label together with the common or generic names of the product. The commodity's net quantity or number needs to be stated. Data on optimal prior to or utilization by i.e. It must state the expiration date. The dimensions of the product must be taken into account when determining whether it

may become unsafe for human consumption and when determining the retail sale price of the package, where the size of the packaging plays a crucial role. In the case that a customer has a complaint, it is crucial to make sure that every shipment contains the name, address, phone number, and email address of the person or office to be contacted. These regulations prohibit adding individual stickers to the box in order to modify or make any kind of declaration. If the product is made up of several components packaged in units to be sold as a single unit, the declarations must be made on the main package or they must be given on separate packages with a notification of the same on the main package [34].[35].

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## 4. Packaging

The packaging of nutraceutical products is important because of the protection of the inner content, their freshness, and potency should be maintained. It is also important because to avoiding contamination and oxidation of the product. The various designs can make a positive impact on the consumer's mind for buying nutraceutical products and nutricosmetics e.g. UK based sports nutrition companies increased 300 % profit after a dramatic design of packaging. The material used in packaging is plastic, glass, paper, metal, etc. The plastic material has a negative impact on the environment or people. The material used other than plastic is sustainable and create a positive impact on the environment and people's.

The alternative for plastic is cardboard to play the role of plastic in packing. The compostable packing gaining popularity for nutraceutical products selling in public and consumers appreciate and accept the product. Another alternative to plastic is a seaweed-based sauce packet that replaces plastic [36].

### 4.1. Protecting nutraceuticals with packaging

A great deal of investigation has been done on the complexity of food ingredients and their possible health advantages (Carpio et al. 20–21). However, meals with greater nutrient contents need to be packaged with more care. Demonstrating Genuineness In order to guarantee that the nutrients are safe and meet consumer expectations, it is crucial that nutraceuticals used as ingredients and in completed products are legitimate. However, it is difficult to obtain essential ingredients to keep up with the exponential rise in consumer nutrient trends. Counterfeiters are generally incentivized to capitalize on the scarcity and occasionally restricted supply of goods. The ability to monitor sources. Getting components to satisfy demand driven by trends is logistically difficult, especially for agricultural items, because The utilization of packaging that promotes nutrient shelf stability makes it easier to obtain nutrients without relying on a limited, expensive, and carbon-intensive chilled supply chain. Before harvesting, they require extensive time frame of growth. An elderberry shortage, for instance, has resulted from low crop yields brought on by unfavorable weather conditions and the strong demand for European black elder berries, which are linked to lowering influenza and cold symptoms. The mismatch between supply and demand has raised questions over the diluting of elderberry within packaging and the substitution of fake elderberry-like chemicals for complete shipments of elderberries.[35]

Nutraceuticals frequently require packaging that offers good moisture and oxygen protection, hence both overt and covert clever packaging are used. To virtually prevent moisture and oxygen passage, Emergen-C 60 mm x 95 mm rectangular single-use packages, for instance, have a 2.7 mil thick multilayer foil laminate barrier. In the event that particle matter unintentionally found its way within the seal region, there would be no loss of seal integrity thanks to the 5.5 mm broad patterned heat sealing across the four sides of the packets. Furthermore, the consumer can easily tear through the portion of the packet that is parallel to and below the top seal tanks to a 2 mm notch on one side seal.

Multiuse nutraceuticals require both an initial barrier and a barrier that persists after the container is opened. For example, consumers must open and close the shrink-labeled jar at least 25 times to reach the gummies in Benefiber Prebiotic Fiber + Probiotics Gummies. The screw-top lid enables a tight seal to be created after the product has been opened, while the inner seal safeguards the product prior to the customer's first opening. For nutrients that need to be kept in an environment with low relative humidity even when used occasionally, moisture-absorbent that stay on the underside of the lidding might be utilized [37].

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## 5. Conclusion

Nutraceuticals is a young industry with enormous growth potential in the years to come. The Dietary Supplement and Health Education Act (DSHEA), which was updated by the US in 1994, lays out the guidelines for registering dietary supplements and nutraceuticals for use in marketing within the nation. To prevent nutritional products from being classified as either food or medication, India has enacted the Food Safety Standards Act 2006 as well as the Food Safety Standard Rules and Regulations 2011. "Functional Foods for special dietary uses" is the term used in India to refer to

nutraceuticals. It is crucial for each new product or entry hoping to join a certain nation's nutraceutical market to adhere to the regulatory framework of that nation; nevertheless, this is dependent on the control over purity, efficacy, and safety. The rate of growth in the nutraceutical industry is significantly faster than that of the food and pharmaceutical sectors. The most prosperous nutraceutical businesses in the years to come will probably be those whose functional products are only one element of a wide range of products that meet conventional and health-conscious value points. The view that consumers have about the connection between nutrition and illness will determine the future demand for nutraceuticals.

To create a reliable and sustainable sector, it is imperative to fund research, inform the public, and encourage ethical behavior. Because the FSSA combined these various laws into a single statute, it may be said that it was a significant milestone. By classifying food products into distinct headings, such as novel foods and genetically modified foods, it sought to provide systematic and scientific development to the food processing business in India. Food that is nutraceutical, standardized, patented, and meant for a certain diet. With the passing of the Food Safety and Standards Act of 2006, India's food safety and standards rules started to become more modern and simplified. Before the FSSAI, there existed uncertainty due to the complex web of laws and procedures governing food safety and standards. Giving suitable and validated information for health usage is a crucial component of health claim labels. Functional food products and nutraceuticals are heavily influenced by health claims. However, each nation has its own regulatory framework for these food goods, and the codex standards state that these health claims are not harmonized globally. These promises should not deceive customers, as per the codex rules. In order to authorize a particular use of a health claim on food labels, the appropriate authorities should control such claims. The United States prohibits claims for illness risk reduction; qualifying health claims are recognized in the United States and Japan but not in India; the kind of claims authorized varies by product. Countries have different laws governing food items' health claims, which makes it challenging to develop a uniform product for the worldwide market. The global market for food items is growing, and regulations pertaining to health claims are posing challenges. Consequently, countries must have uniform laws in order to achieve the health claims for food-derived goods' benefits and to produce food that is related to health.

Revising nutrition labeling regulations might help inform consumers about the safe and nutritious qualities of nutraceuticals, much like the U.S. Nutrition Labelling Education Act of 1990 did. For customers to make informed judgments, labels must be clear and instructional. Together, public and private sector organizations can advance legislation that encourages the growth of the nutraceutical business with the assistance of food scientists. Legislation that is both clear and encouraging promotes investment, innovation, and adherence to safety and quality requirements. The industry can grow greatly as a result of initiatives including new retailing programs, more clinical research and validation, media and government focus, more awareness through heightened campaigns, and greater corporate responsibility through health awareness programs.

These recommendations are intended to encourage cooperation, standardize procedures, broaden standards, modify legislation, and prioritize research and development in order to improve the regulatory framework and support the expansion of the functional food/nutraceutical industry in India. Enhancing visibility and competitiveness in the global market can be achieved by encouraging Indian producers to get together and create a platform for marketing India as a brand in the nutraceutical business. Enhanced cooperation between research and development and manufacturing can result in resource sharing, synergies, and faster industry advancement. Nutraceutical product quality and safety must be consistently ensured by standardization in production, validation, research and development, and intellectual property protection. Effective standard development and implementation need coordinated efforts from legislators, regulators, and manufacturers.

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## Compliance with ethical standards

### *Disclosure of conflict of interest*

No conflict of interest to be disclosed.

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