REVIEW ARTICLE

Current trends and regulatory aspects of nutraceutical: A comprehensive review

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Abstract

In 1989, the Foundation for Innovation in Medicine (New York, US) created the term "nutraceutical" to name the rapidly expanding area of biomedical research. Nutraceuticals are defined as food or dietary components that offer medical or health benefits to the body, including disease prevention and treatment. Nutraceuticals are viewed as a more natural way to achieve therapeutic effects with fewer side effects, and this perspective has transformed the development and production of nutraceuticals into a multi-billion-dollar industry. The nutraceutical market is expected to reach $1025 billion by 2030, with a CAGR of 8.33% from 2022 to 2030. Nutraceuticals are gaining popularity due to their potential nutritional, safety, and therapeutic benefit. Current research has demonstrated that these chemicals have potential results in a variety of complications. The regulatory status of nutraceuticals varies by country or region. The food and drug administration (FDA) regulates nutraceuticals as dietary supplements in the United States under the dietary supplement health and education act (DSHEA) of 1994. According to this regulation, dietary supplements are products with one or more nutritional components, such as vitamins, minerals, herbs, or other botanicals, that are meant to supplement the diet. Nutraceuticals do not require FDA pre-market approval under DSHEA, and the manufacturer is responsible for product safety and labeling. The FDA, on the other hand, has the jurisdiction to investigate companies that make false or misleading statements about the safety or effectiveness of their products. This article provides a brief overview of the nutraceuticals regulation established by the US FDA in the United States and the Food Safety Standard Authority of India in India. Finally, the nutraceutical industry is expanding rapidly, due to rising consumer awareness of the necessity of leading a healthy lifestyle. Regulatory authorities around the world are responsible of guaranteeing the safety and efficacy of nutraceuticals, and rules vary from country to country. As the market expands, it is critical for regulatory agencies to stay ahead of the latest industry advancements to protect customer safety and trust.

Key words: Dietary supplements, health benefits, multibillion-dollar industry, nutraceuticals, regulatory aspects

INTRODUCTION

Kurt Lewin said "No research without action, no action without research" – From the start of human history, mankind has devoted a deep interest in, and concern about, the continuity of food supply. Long before the development of medical science, philosophers and later physicians paid attention to the importance of daily nutrition in human and public health.[1] Many natural herbal plants, including turmeric, gooseberry, garlic, ginger, honey, aloe vera, pomegranates, and many others, are used by humanity as food and medicine.[2] Surprisingly, there was not much of a distinction between food and drugs from the time of Hippocrates (460–377 BC) until the advent of modern medicine. The careful selection of natural food products was essentially how medication was used. Hippocrates, a Greek physician, popularized the idea that food might be used as medicine by suggesting, "Let food be the medicine and medicine be the food."[3] Due to the increased use of harmful man-made substances such as insecticides, toxic metals, and electromagnetic radiation, industrialization and changing work cultures have resulted in significant land, water, and food contamination. Simultaneously, economic progress has dramatically altered human habits, transforming into fast food societies with declining nutritious quality. Therefore, a variety of diseases, such as diabetes, obesity, different malignancies, neurodegenerative disorders, physiological issues, hyperlipidemia, chronic inflammatory, cerebrovascular diseases, osteoporosis, arthritis, and a host

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of others, are developing more frequently due to nutritional deficiencies.[4] Stephen DeFelice, MD, founder and chairman of the foundation for innovation in medicine, Cranford, NJ, introduced the term "Nutraceuticals" in 1989 by combining the words "nutrition" and "pharmaceutical" [Figure 1]. According to DeFelice, a nutraceutical is "a food (or part of a food) that provides medical or health benefits, including disease prevention and/or treatment." The term nutraceutical is commonly used in the marketing industry but there is no regulatory definition. The term is used to describe to depict a variety of items that isolated from individual nutrients and to herbal products, dietary supplements, and processed food such as soups, cereals, and beverages [Figure 2].[5] In India, the use of nutraceutical supplements is continuously rising due to several concerning facts such as: walking decreased by 60%, exercise and jogging decreased by 50% game and sports are recreational activities decreased by 50%, low activity entertainment such as computer, DVD use has gone up, and desk job increased by 80%. By 2030, according to the WHO, India would account for 60% of all cardiac patients worldwide, and there will be 190 million instances of diabetes in Asia, with more than half of those cases occurring in China and India. According to statistics, the overweight/obese people in India will increase up to 24% till the end of 2025. The reason for escalating the use of nutraceuticals includes: Increasing costs of drug and surgical procedure; increasing risk of side effects in long-term use of drugs, nutraceuticals highly beneficial in chronic disease, increasing awareness in person and believing more in prevention than a cure; and person who has chronic diseases and have found no solution in allopathic medicines. Products are reasonably priced and cost-effective for the general public; however, food processing may leave out essential elements for optimum health.[6,7]

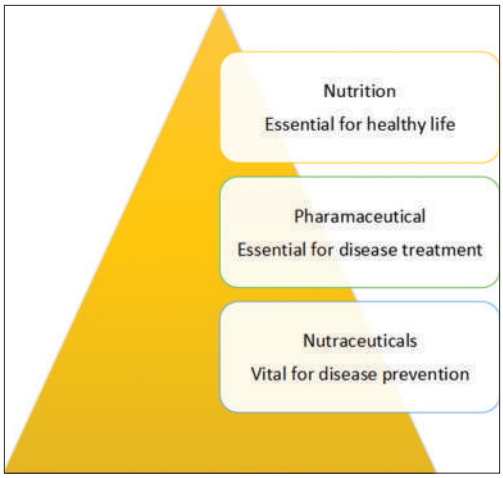

Figure 1: Pyramid that shows the importance of nutrition, pharmaceutical and nutraceuticals

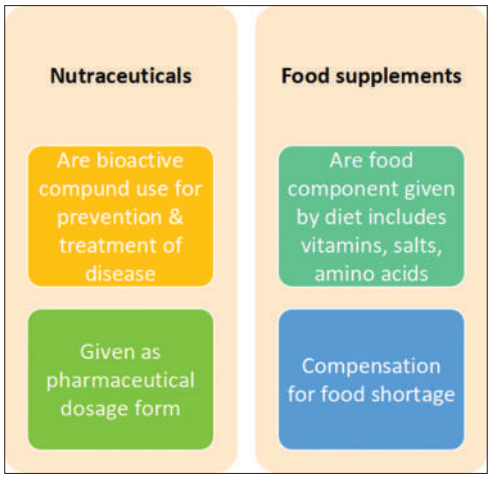

Figure 2: Difference between nutraceuticals and food supplements

CLASSIFICATION OF NUTRACEUTICALS

There are numerous methods to categories nutritional supplements, including by their source, purpose, and mechanism of action [Figure 3]. Here are some typical categories for nutraceuticals:

1. Natural products: Those nutraceuticals that are isolated from natural sources such as plant extracts, herbs, and animal products
2. Dietary supplements: Nutraceuticals that are meant to be taken as a supplement the regular diet and are available in various forms such as capsules, tablets, powders, and liquids
3. Functional foods: Foods that have a beneficial effect on health beyond their basic nutritional value, such as probiotics, prebiotics, and fortified foods
4. Medical foods: Nutraceuticals that are formulated to meet specific nutritional need for the management of a medical condition, such as metabolic disorders, gastrointestinal disorders, and immune deficiencies
5. Cosmeceuticals: Nutraceuticals used in topical applications for cosmetic purposes, such as anti-aging creams, skin brighteners, and hair growth products
6. Phytochemicals: Nutraceuticals derived from plants that have been shown to have health benefits, such as polyphenols, carotenoids, and flavonoids
7. Nutritional supplements: Nutraceuticals that provide nutrients that are lacking in the diet, such as minerals, vitamins, and amino acids
8. Herbal products: Nutraceuticals that are derived herbs or medicinal herbs such as ginseng, echinacea, and valerian that have been used for centuries in traditional medicine [Figure 3].[4]

GLOBAL NUTRITIONAL SUPPLEMENTS MARKET

The worldwide nutraceuticals market will experience a compounded yearly growth rate of 7.5%, with an increase in value from $198.7 billion in 2016 to $285.0 billion in 2021. In addition, the functional beverages market is predicted to grow from $71.5 billion in 2016 to $105.5 billion in 2021, with a compounded yearly growth rate of 8.1% over the same

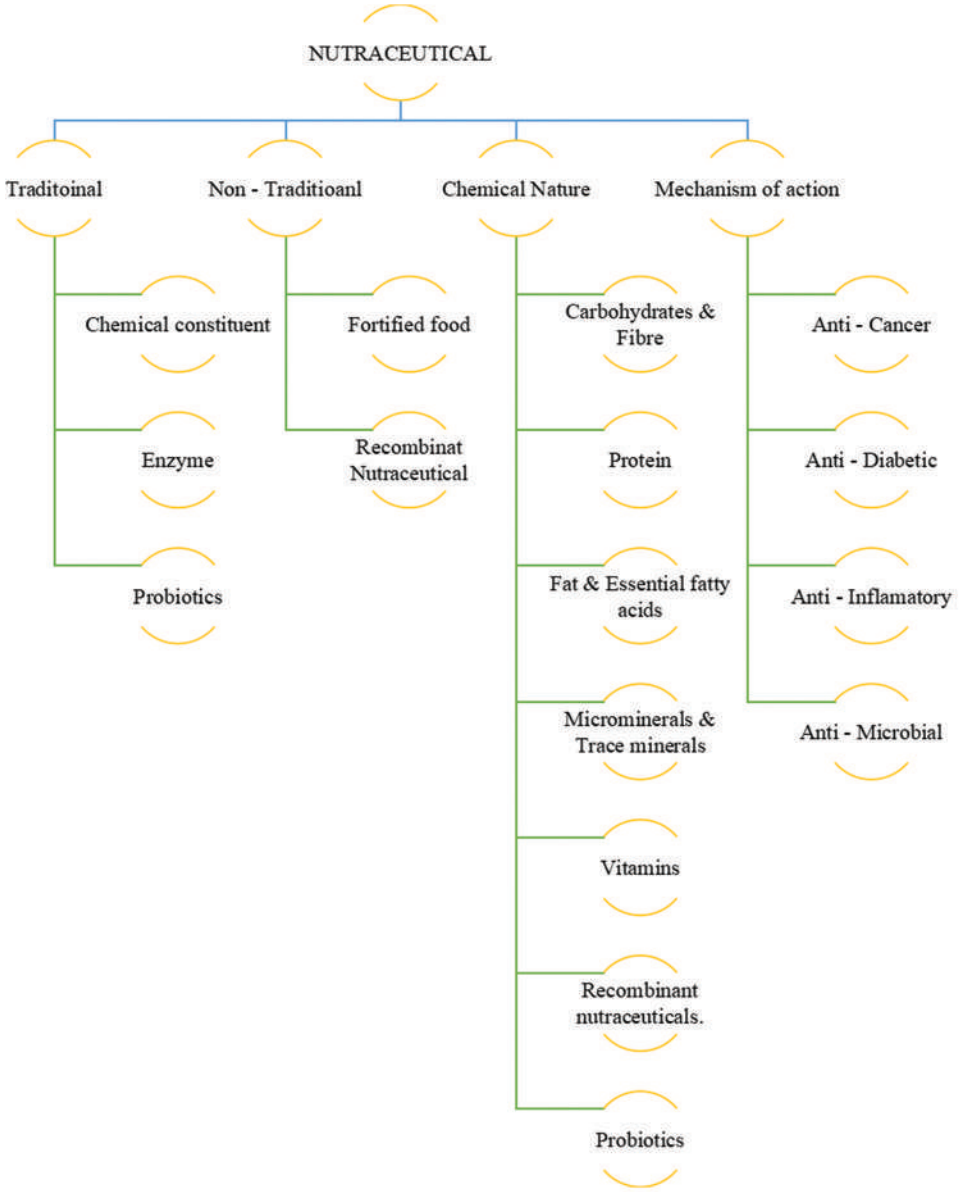

Figure 3: Classification of nutraceuticals

period. The US market for nutritional supplements is the biggest and most developed at the moment. Between 2012 and 2016, it grew at a compound annual growth rate of 10%, going from $50 billion to $65 billion. According to reports, the United States (36%), Asia Pacific (30%), Europe (30%), and Other (8%) accounted for the majority of global nutraceutical market consumption in 2015. Many market assumptions for nutraceuticals have been emphasized, including Market Size [Figure 4].[8]

NUTRACEUTICALS' POTENTIAL HEALTH EFFECTS

Nutraceuticals are believed to provide a wide range of potential health benefits due to their ability to modulate biological processes in the body. Here are some examples of the potential health benefits of nutraceuticals with references:

1. Cardiovascular health: Studies have demonstrated that soluble fiber, plant sterols, and omega-3 fatty acids all of these have a positive impact on heart and blood vessel health as they decrease cholesterol levels and blood pressure
2. Cognitive function: Certain supplements, such as ginkgo biloba and omega-3 fatty acids, have been demonstrated to enhance memory and cognitive function
3. Immune system: It can be strengthened by consuming dietary supplements such as vitamin C, vitamin D and probiotics, which are known to reduce inflammation and support the growth of beneficial bacteria in the gut
4. Bone health: It has been demonstrated that nutritional supplements including calcium, vitamin D, and vitamin K can enhance bone health and lower the risk of osteoporosis

5. Effects on inflammation: Studies have demonstrated the anti-inflammatory properties of nutraceuticals such as curcumin, resveratrol, and omega-3 fatty acids in the body. These properties might reduce the risk of chronic ailments such as cancer and heart disease
6. Gut health: It has been shown that supplements such as probiotics and prebiotics can improve gut health but reducing inflammation and increasing the growth of beneficial bacteria in the gut.
7. Skin health: It has been shown that antioxidants and nutraceuticals, like collagen peptides, can enhance skin health by decreasing signs of aging and improving skin elasticity [Figure 5].[9,10]

DIFFERENCE BETWEEN NUTRACEUTICALS AND PHARMACEUTICALS

Pharmaceuticals and nutraceuticals are two categories of items that are used to cure illnesses and promote health, but they differ in terms of content, regulatory restrictions, and clinical testing standards [Figure 6].

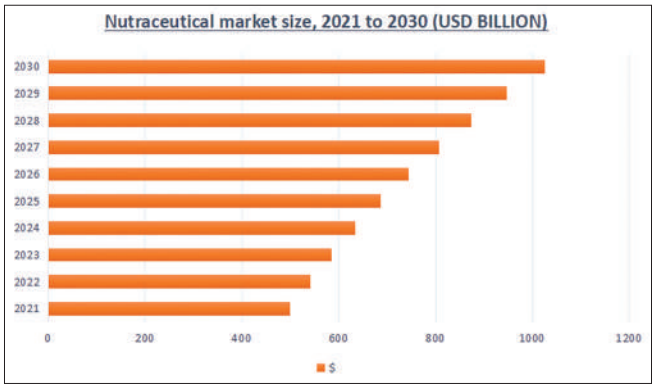

Figure 4: Bar graph that shows the projection of nutraceutical market size in upcoming years

Nutraceuticals, commonly known as dietary supplements, are goods that include natural components including vitamins, minerals, herbal extracts, and probiotics and are meant to offer health advantages above and above those of basic nutrition. According to the food and drug administration (FDA), the dietary supplement health and education act (DSHEA) of 1994 defines dietary supplements as products that are meant to supplement the diet such as tablets, capsules, or liquids and are not considered medications. This law also governs nutraceuticals, which are subject to specific safety and labeling regulations. While nutraceuticals are noot required to undergo the same level of testing and clinical trials as pharmaceuticals, they still need to comply with certain regulations. The FDA mandates that all labels for nutraceuticals have accurate information about the components, dose, and possible side effects. In addition, manufacturers must adhere to good manufacturing procedures to guarantee the products' quality and purity. Contrarily, pharmaceuticals are goods created specially to treat diseases and medical situations, and the FDA imposes tight regulations on them. The FDA defines pharmaceuticals as drugs used to prevent, diagnose, mitigate, treat, or cure diseases and they are regulated under the federal food, drug and cosmetic act. Before being given FDA approval for usage, pharmaceuticals must undergo thorough research and clinical studies to show their safety and efficacy. The FDA also stipulates that drugs must be produced in accordance with tight regulations and standards to guarantee its quality and purity. While both medicines and nutraceuticals can be used to treat illnesses and promote health, it is crucial to grasp the differences between the two and utilize each product type only when prescribed by a health-care professional.[11,12]

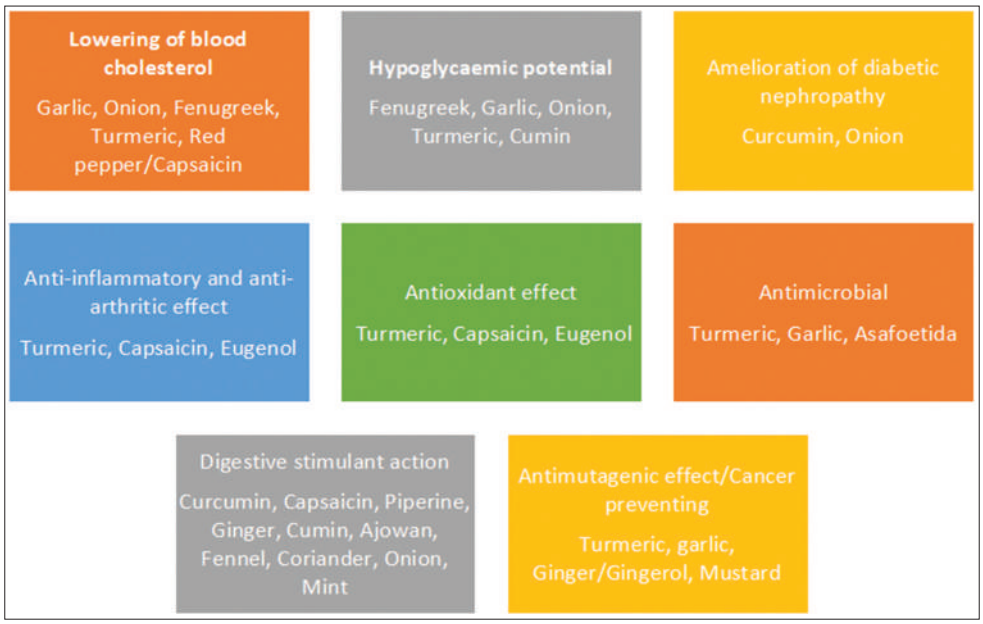

Figure 5: Natural foods and their medicinal use

PROPOSED STRATEGY FOR DEVELOPING NEW NUTRACEUTICALS

The development of new nutraceuticals requires a rigorous and systematic approach to ensure their safety, efficacy, and regulatory compliance. Here is a proposed protocol for the development of new nutraceuticals, based on industry best practices and scientific literature:

1. Identify a market need: The first step in developing a new nutraceutical is to identify a market need. This may involve examining scientific literature, consumer preferences, and market trends to pinpoint potential health advantages that are not presently being met by existing products
2. Conduct a feasibility study: Once a market need has been identified, a feasibility study should be conducted to assess the scientific and commercial viability of the product. This can involve evaluating the safety and efficacy of potential ingredients, assessing the regulatory landscape, and estimating the potential market size and profitability
3. Develop a formulation: Based on the results of the feasibility study, a formulation for the new nutraceutical should be developed. This may involve testing different combinations of ingredients to optimize safety, efficacy, and consumer acceptance
4. Conduct preclinical testing: Before human trials can be conducted, preclinical testing should be performed to assess the safety and efficacy of the nutraceutical in animals. This can involve evaluating the pharmacokinetics, toxicity, and pharmacodynamics of the product
5. Conduct human clinical trials: Once preclinical testing has been completed, human clinical trials should be conducted to evaluate the safety and efficacy of the nutraceutical in humans. These trials should be designed to meet regulatory requirements and should be conducted in accordance with good clinical practice guidelines
6. File for regulatory approval: After the clinical trials have been completed, regulatory approval should be sought from the appropriate authorities. This may involve

Figure 6: Nutraceuticals versus pharmaceuticals

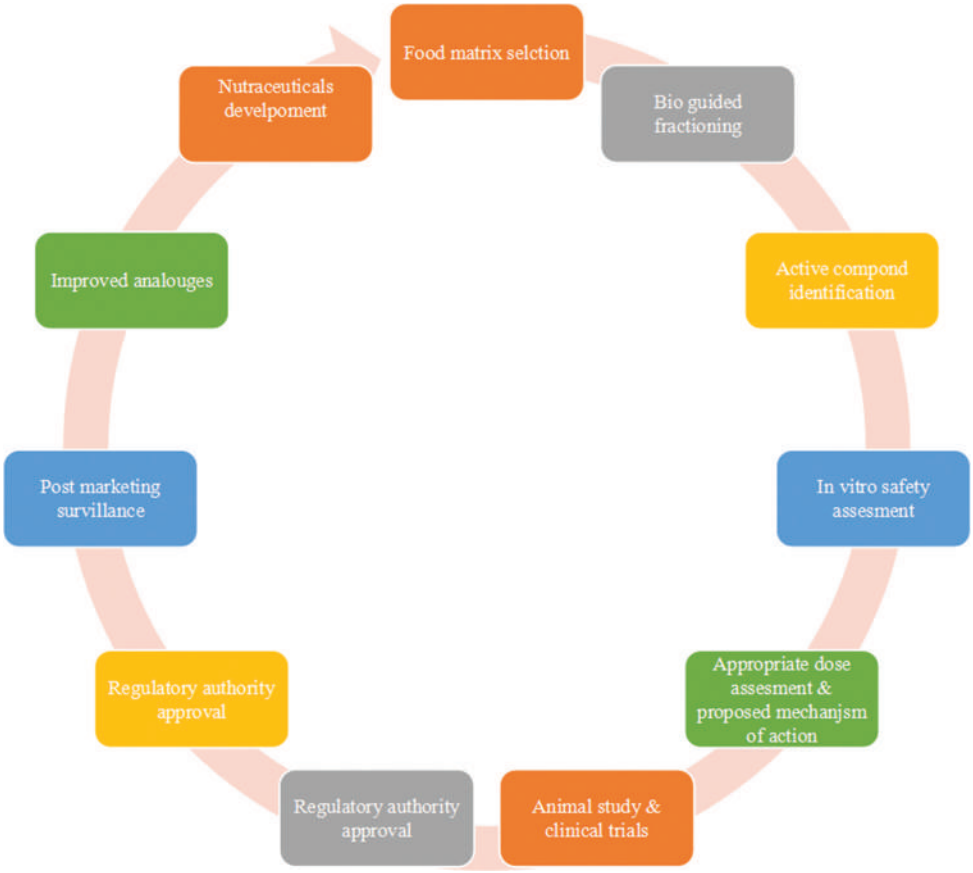

Figure 7: Flowchart that represents the process of development of new nutraceutical

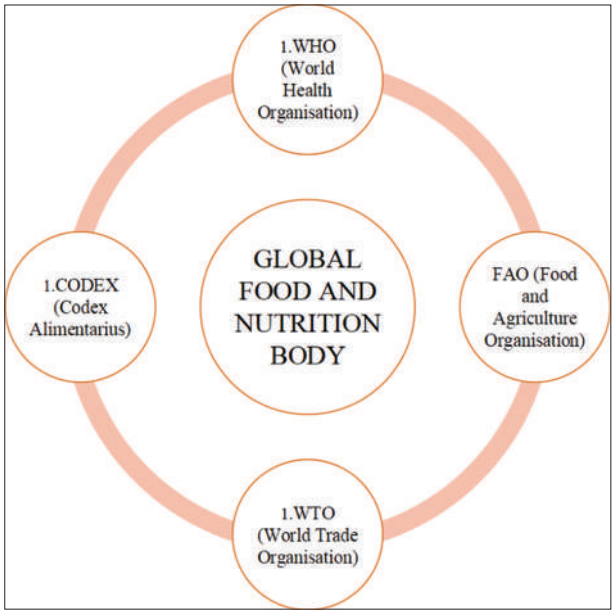

Figure 8: Chart of top global food and nutrition regulatory body

submitting a new dietary ingredient notification to the US FDA or filing for a health claim in the EU

7. Launch the product: Once regulatory approval has been obtained, the nutraceutical can be launched in the market. Ongoing post-marketing surveillance should be conducted to ensure the safety and efficacy of the product and to monitor for any adverse events [Figure 7].

Overall, the development of new nutraceuticals requires a comprehensive and multi-disciplinary approach, involving expertise in science, marketing, and regulatory affairs. By following a systematic and evidence-based protocol, developers can maximize the chances of success and ensure the safety and efficacy of their products.[13-15]

REGULATORY ASPECTS

The primary regulations governing the nutraceutical industry are the DSHEA, which was enacted in 1994. In addition, the

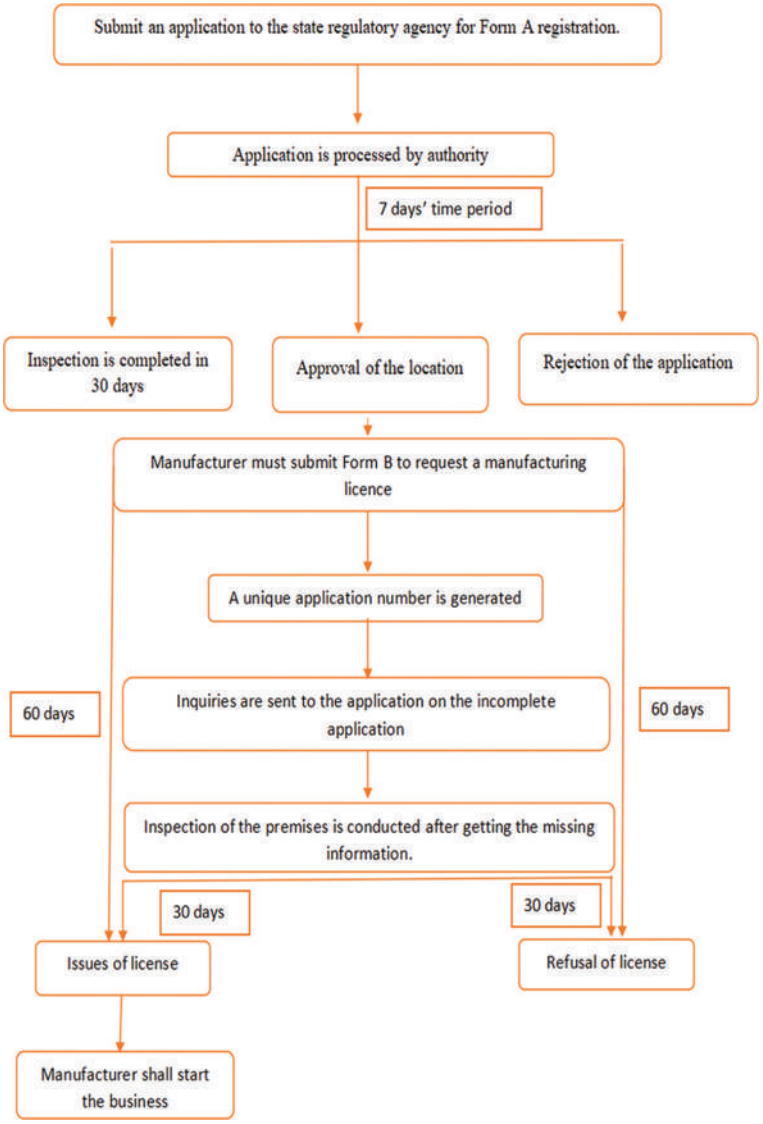

Figure 9: The regulatory procedure used in India

Figure 10: The regulatory procedure used in USA

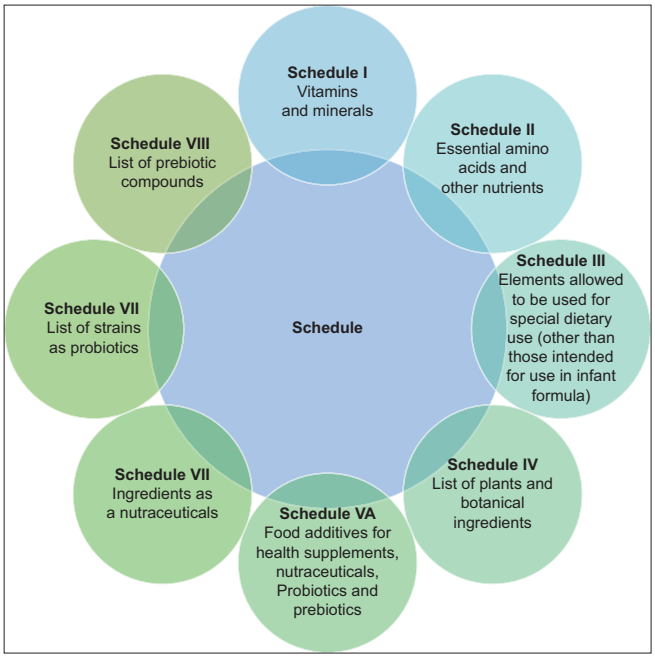

Figure 11: Types of schedules

Food Safety and Standard Authority has released regulations for good business licensing and registration, manufacturing, packaging, labeling, and food product standards. The Food Safety and Standard Rule and Regulations went into effect in August 2011. Manufacturers of goods will be encouraged by this rule to create reliable procedures and carry out clinical testing. The Foreign Direct Investment Act, which was implemented in 2012, gave foreign businesses additional opportunities to produce and market dietary supplements in India. There is therefore only one authority in India with the authority to.[16]

REGULATORY CHALLENGES

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:

1. 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
2. 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
3. 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
4. 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 purity. This can make it difficult to establish consistent quality standards for these products
5. 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
6. 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.[17,18]

INTERNATIONAL REGULATORY BODIES FOR NUTRACEUTICALS

Numerous international regulatory organizations oversee nutraceuticals to ensure their safety, effectiveness, and quality [Figure 8]. These are a few of the main organizations that oversee nutraceuticals on a global level [Table 1]:

1. U.S. FDA: The FDA is responsible for regulating dietary supplements and nutraceuticals in the United States. The agency requires that dietary supplements be safe, properly labeled, and manufactured in a quality manner. The FDA also has the authority to remove unsafe or mislabeled products from the market.
2. European food safety authority (EFSA): The EFSA evaluates the safety and efficacy of food ingredients, including nutraceuticals, in the European Union. The agency provides scientific advice and recommendations to the European Commission on the safety of food and feed
3. Health Canada: Health Canada is responsible for regulating natural health products, including nutraceuticals, in Canada. The agency requires that natural health products be safe, effective, and of high quality. Health Canada also has the authority to recall unsafe products from the market
4. Therapeutic goods administration (TGA): The TGA regulates therapeutic goods, including nutraceuticals, in Australia. The agency requires that therapeutic goods be safe, effective, and of high quality. The TGA also has the authority to recall unsafe products from the market
5. China FDA (CFDA): The CFDA regulates dietary supplements and nutraceuticals in China. The agency requires that dietary supplements be safe and properly labeled. The CFDA also has the authority to remove unsafe or mislabeled products from the market
6. Ministry of health, labor, and welfare (MHLW): The MHLW regulates health foods, including nutraceuticals, in Japan. The agency requires that health foods be safe and properly labeled. The MHLW also has the authority to recall unsafe products from the market
7. Food Safety and Standards Authority of India (FSSAI): The FSSAI regulates food and nutraceuticals in India. The agency has established standards for food and nutraceuticals and regularly inspects and tests products to ensure compliance with these standards.

These international regulatory organizations are essential in making sure that nutraceutical products are safe and of high quality anywhere in the world. These organizations require consumer protection and the ethical growth of nutraceuticals by setting standards, carrying out inspections and testing, and enforcing rules.[19]

REGULATIONS OF NUTRACEUTICALS 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.[21-23]

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 [Figure 9]. A description of the regulatory procedure:

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

US Regulatory Process

Nutraceuticals are dietary supplements, according to the USFDA, whose regulations date back to 1994. Dietary supplement products and their ingredients are governed by a different set of rules by the FDA. Under the Dietary Supplement Health and Education Act (DSHEA):

- Products that are contaminated or misbranded may not be marketed by manufacturers and distributors of dietary supplements and dietary components.

Table 1: Classification of nutraceutical products for each country based on the governmental agency and the regulatory guidelines[20]

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 (CAA) 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 states	Food and drug Administration (FDA)	Food safety Modernization Act (FSMA), 2011

- After a dietary supplement product enters the market, the FDA is responsible for taking action against it if it is adulterated or misbranded Figure 10].

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 [Figure 11].

The following products are covered by these regulations: (a) Nutraceuticals (Nutra); (b) HS; (c) FSMP; (d) FSDU; and (e) Pre-Pro.[22]

CONCLUSION

To meet consumer demand, the nutraceutical industry is rapidly growing and adding new products and delivery methods. However, with this growth comes increased scrutiny from regulators, who are closely monitoring the activities of companies and imposing stricter regulations to ensure compliance and protect consumers. Manufacturers of nutraceuticals are required to ensure the efficacy, safety, and compliance with all legal requirements of their goods. The trend toward personalized nutrition and natural ingredients is likely to continue, as consumers seek products that are tailored to their individual needs and preferences.

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