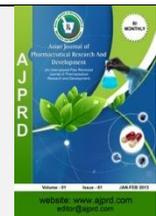


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Review Article

India's Growing Demand of Nutraceuticals

Saqlain Ahmad

Department of Hospital Management and Hospice Studies, Jamia Millia Islamia, Jamia Nagar, India. -110025

ABSTRACT

Nutraceuticals are nutritive ingredients—a cross between food and medicine—that are physiologically active and have the power to preserve optimum health and advantages. These goods are essential to maintaining human health and well-being, especially in light of upcoming treatment advancements. Due to their safety profile, medicinal effects, and nutritional advantages, nutraceuticals have gained popularity. Global demand for nutraceuticals is rising in the areas of disease prevention, health care promotion, and other services. In this overview, several drug-nutritional interactions are additionally outlined using a variety of instances. The concluding portion of the assessment states that there are several patents on nutraceuticals for use in agriculture and in treating a variety of disorders, confirming the exponential rise of the market for nutraceuticals. In addition to being used for nutrition, nutraceuticals have been employed as an adjunct treatment for both the prevention and the treatment of a number of disorders, including the reduction of adverse effects from radiation and chemotherapy for cancer. Nutraceutical formulation development presents a number of obstacles that are often solved by a variety of innovative nano-formulation techniques. Any negative effects of nutraceuticals products may be avoided with the aid of prior knowledge about different medication combinations. Moreover, micronized food items along with additional nutraceutical supplements with enhanced health advantages are produced thanks to nanotechnology. The most recent significant results (clinical research) on nutraceuticals that demonstrate the bioactive compounds in these supplements have a therapeutic effect on a range of ailments have also been included in this review article.

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*Address for Correspondence:

Sarah Khan, Department of Hospital Management and Hospice Studies, Jamia Millia Islamia, Jamia Nagar, India.-

INTRODUCTION:

Nutraceuticals are defined as “specially designed preparations” that are made to meet certain nutritional needs and/or provide preventative healthcare. Nutraceuticals are formulated nutrients that, when added to a supplement diet, aid in the prevention and treatment of certain illnesses. Dr. Stephen De Felice coined the phrase “nutraceutical” in 1989, combining the words “pharmaceutical” and “nutrition.” These are foods, or portions of meals, that are good for treating and/or preventing diseases, among other health advantages. The field of nutrition science has expanded its knowledge to include human health, the prevention and treatment of chronic illnesses, and the early detection of nutritional shortages [1,2].

The terms “dietary supplements,” “food supplements,” and “nutraceuticals” have developed since Dr. De Felice first

proposed the idea. The distinction made by regulatory bodies regarding food supplements and nutraceuticals is not very clear. Recent research has focused on reframing the notion of nutraceuticals to take these items' toxicity, safety, and efficacy into account. Food items are nutritious substances that are consumed orally or through other means in order to support life, give off energy, and encourage development. Nutrient separation from various dietary sources is currently widely acknowledged and applied. The selection of an epidemiological target is the first step in differentiating food/dietary supplements from nutraceuticals [3]. This is followed by safety and effectiveness studies that clarify the mechanism of action.

Identifying “food supplements” as agents to make up for deficits in micro- or macronutrients is one way to distinguish between these two types of formulations; moreover, the use of a “nutraceutical” in the treatment of a pathological illness needs to be backed by substantial

scientific evidence. Nutritional supplements should have a solid safety profile with minimal unfavourable side effects and improved bioavailability based on sufficient clinical data [4]. The distinction between two types of formulations is quite thin; while the same chemicals may function as a food supplement or nutraceutical, they may be distinguished differently based on claims. Food supplements comprise single or mixtures of minerals, vitamins, protein supplements, functional foods, and herbal items; nutraceuticals comprise single or combinations of pro- and pre-biotic foods and food for specific medicinal reasons [5,6]. Incorporating nutraceuticals into a regular diet may help avoid pathological illnesses by extending or eliminating the requirement for pharmaceuticals in people who are candidates for nonpharmacological alternative treatments for pathological conditions. There are suggestions that some meals, such as those with spices and herbs, have the potential to lower the risk of a number of diseases and can significantly enhance quality of life [7].

Nutraceuticals provide a wealth of advantages, including their promising outcomes in both the avoidance and management of complex illnesses. Nutraceuticals must be administered and prescribed, nevertheless, and their usage must be tightly controlled to avoid unintended consequences and uncontrollable use. To increase the efficacy and bioavailability of drug compound-based nutraceuticals, several researchers have investigated them. Even in pregnant women, the safety and effectiveness of several statins have been utilised to prevent cardiovascular disorders [8,9]. When used in conjunction with conventional drug therapy, nutraceuticals with a well-established safety profile and proven influence on pregnancy may be a viable therapeutic alternative for avoiding diabetes mellitus and hypertensive diseases. Potentially effective options for innovative nutraceuticals include calcium, omega-3 polyunsaturated fatty acids, vitamin D, folic acid, resveratrol, alpha-lipoic acid, zinc, inositol, and probiotic supplements.

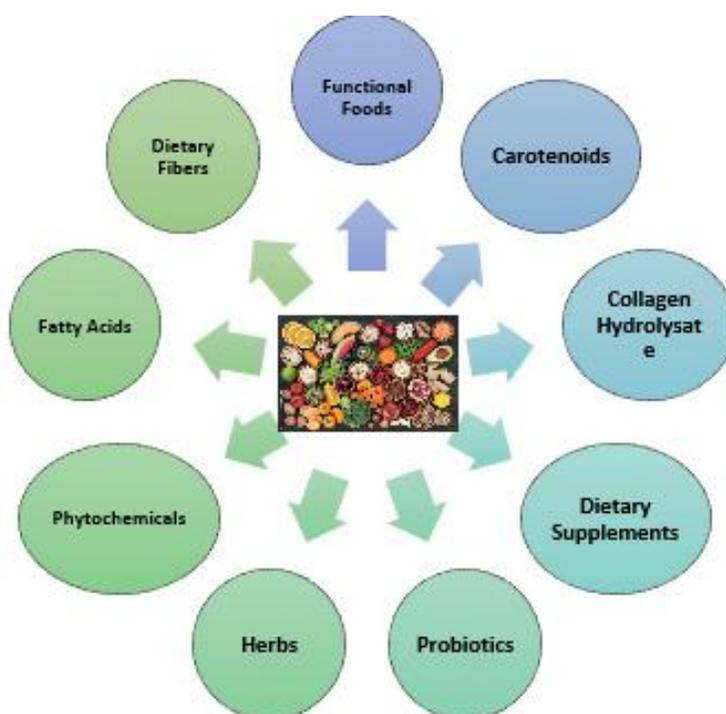


Figure 1: Nutraceuticals

Researchers have assessed the nutraceutical linked to the medication ezetimibe for those who are susceptible to elevated statin levels, which worsen cardiovascular disorders [10,11]. Enhancing its safety and effectiveness for commercial usage, the combination of a new nutraceutical and non-steroidal anti-inflammatory medicines (NSAIDs) has been demonstrated as a possible contender for osteoarthritis. Nutraceuticals including antioxidants, omega-3 fatty acids, plants like wheatgrass, aloe vera, seaweed, and algae, as well as teas and herbs like ginseng and Echinacea, continue to enjoy a healthy and expanding market [12]. According to a recent assessment, the nutraceutical industry is predicted to grow to a potential value of \$340 billion by 2024, indicating that it is now experiencing worldwide expansion. From 2016 to 2024, the cumulative annual

growth rate (CAGR) for nutraceuticals is projected to be 7.2%. Approximately 90% of the worldwide nutraceutical industry is now accounted for by Europe, the United States, and Japan [13]. At a compound annual growth rate of 8%, the market is expected to grow from \$247 billion in 2019 to \$336 billion by 2023. Now that the global markets have reached a certain level of maturity, developing economies, particularly those in Asia Pacific, including India, are the focus of nutraceutical companies [14,15].

Indian Pharmaceutical Industry

In 2017, the market share of the Indian nutraceutical industry was a mere 2% of the worldwide market. At a 21% CAGR, it is predicted to reach \$11 billion by 2023.

Additionally, it is anticipated that India would account for at least 3.5% of the worldwide market by 2023 [16].

Market Overview:

- **Rapid Growth:** The Indian nutraceutical industry has been growing rapidly, driven by factors such as increasing health awareness, a rising middle class, and a growing aging population.
- **Diverse Product Range:** The industry covers a diverse range of products, including vitamins, minerals, herbal supplements, probiotics, omega-3 fatty acids, functional foods, and beverages enriched with health-promoting ingredients [17].
- **Government Support:** The Indian government has shown support for the nutraceutical sector through policies that encourage investment and innovation. Initiatives like 'Make in India' and 'Ayushman Bharat' have indirectly benefited the industry.

Factors Driving Growth:

- **Health Consciousness:** Growing awareness of health and wellness among consumers has led to an increased demand for nutraceutical products as people seek preventive healthcare solutions.
- **Urbanization and Lifestyle Changes:** Urbanization and changes in lifestyle, including sedentary habits and poor dietary choices, have contributed to the rise in health issues, prompting individuals to turn to nutraceuticals for support [18].
- **E-commerce Boom:** The surge in e-commerce platforms has facilitated easier access to a wide range of nutraceutical products for consumers across the country.
- **Traditional Ayurveda and Herbal Products:** The rich heritage of traditional Indian medicine, particularly Ayurveda, has led to the popularity of herbal and Ayurvedic nutraceuticals both within India and globally [19].

Challenges:

- **Regulatory Compliance:** The nutraceutical industry faces challenges related to regulatory compliance and standardization of products. Efforts are being made to establish clear regulations to ensure the safety and efficacy of nutraceutical products.
- **Consumer Education:** Despite increasing awareness, there is a need for continued consumer education regarding the benefits and proper usage of nutraceutical products.
- **Quality Control:** Maintaining consistent quality across products remains a concern, and efforts are ongoing to establish and adhere to quality standards [20].

Opportunities:

- **Innovation:** There is significant scope for innovation in the development of new nutraceutical products, formulations, and delivery systems.

- **Export Potential:** The Indian nutraceutical industry has the potential to expand its global presence, capitalizing on the growing demand for natural and Ayurvedic products worldwide [21,22].
- **Collaboration:** Collaboration between industry players, research institutions, and government bodies can foster growth and development in the sector.

Every industry is feeling the effects of the COVID-19 pandemic. At this point, it is difficult to forecast the long-term effects. Following the COVID-19 pandemic, the world economy is still having difficulty, and this is having an increasing influence on international commerce and the nutraceuticals sector. Despite strong demand, the supply of goods is rapidly deteriorating [23]. With 75–80% of the raw materials used in nutraceuticals coming from China, the sector cannot fill the gap among tremendous demand and limited supply in North America, Europe, and Asia Pacific. The production of nutraceuticals has decreased as a result of the abrupt recessive circumstances in native regions and China's suspension of manufacturing. Customers' demand for dietary supplements increased dramatically, indicating that these products boost immunity and reduce potential health risks [24].

Nutraceuticals used in cardiovascular diseases

1. Alicin and Alliin

Raised levels of blood cholesterol and plasma triglycerides are linked to atherosclerosis and ischemic heart disease. As an antihyperlipidemic, allium sativum works by reducing endogenous cholesterol production as well as the excretion of large quantities of cholesterol and its byproducts in the faeces [25,26]. This contributes to a more desirable HDL/LDL ratio. If stomach acids are able to preserve cholesterol levels, then alicin and alliin may have an influence on them. A total of 781 individuals participated in thirteen placebo-controlled studies to evaluate the effects of garlic supplementation on serum cholesterol. In addition to being antihyperlipidemic, garlic has some intrinsic antihypertensive properties [27,28].

2. Omega-3 Fatty Acids

Polyunsaturated fatty acids (PUFAs) are omega-3 fatty acids that come from marine sources. In the treatment and avoided development of cardiovascular disorders, docosahexaenoic acid (DHA) and marine omega-3 eicosapentaenoic acid (EPA) are essential. In one research, the diet and reinfarction experiment (DART), a randomised trial included 2033 men who had suffered a myocardial infarction, found that taking fish oil supplements decreased death rates by 29% over the course of two years [29,30]. Fish oil consumption resulted in a notable 45% drop in unexpected deaths, a 30% decrease in deaths from cardiovascular illnesses, and a 20% decrease in total mortality. Modern clinical trial studies have demonstrated that omega-3 fatty acids not only aid patients with atherosclerosis-related plaque development, but they also reduce the risk of cardiac arrhythmias. Omega-3 fatty acids prolong the heart's relative refractory time and aid in the

treatment of arrhythmias by improving the electrical stability of cardiac cells [31].

3. Soy Isoflavones

The biological plausibility of observational relationships is supported by the antihyperlipidemic, antihypertensive, anti-hyperglycemic, antioxidant, anticancer, anti-inflammatory, anti-obesity, and neuroprotective properties of soy proteins and isoflavones, which are significant nutrients with potential medicinal benefits. Reports from clinical studies clearly show that soy protein intake lowers blood cholesterol levels in people. Furthermore, the USFDA has provided data showing postmenopausal women's blood pressure decreased when they consumed 25 grammes of soy proteins or isoflavone daily. Furthermore, soy proteins have a positive impact on blood lipid levels, particularly in those with high cholesterol. In one study, individuals fed a diet low in saturated fat had a reduction in their chance of developing coronary heart disease [32]. Lipid profiles were unaffected by soy isoflavone. Additionally, a research found that consuming novel soy products with high quantities of isoflavones, cotyledon soy fibre, and soy phospholipids (Abaco and Abalon) significantly reduced the ratio of LDL to HDL.

4. Proteins, Peptides and Amino Acids

Heart conditions and hypertension are related. Angiotensin converting enzyme (ACE) inhibitors have been the mainstay of treatment for the illness; however, these medications have a number of adverse effects, including rashes, coughing, hypotension, increased potassium levels, and reduced renal function. Casein and whey protein that are obtained from milk include naturally occurring ACE inhibitors. Studies on animals have also demonstrated the antihypertensive properties of these milk-derived proteins [33]. Clinical investigations that have shown an independently significant hypotensive impact have reported similar findings.

5. Antioxidant Vitamins

Potential dietary supplements containing antioxidants have been utilised to treat chronic illnesses including cancer and cardiovascular disease. They mitigate the deleterious impact of free radicals, hence decreasing the oxidation of LDL cholesterol. Antioxidant vitamins are abundant in vegetables, fruits, fish, and fixed oils. They function by either entrapping or inhibiting the generation of oxygen free radicals. Several epidemiologic investigations into CHD patients who consume high levels of antioxidant-rich foods have shown that these individuals experience lower rates of morbidity and death. Vitamin E and C antioxidant supplements aid in the prevention of CHD [34,35]. Nevertheless, β -carotene supplementation is not advised as it may have negative consequences. The National Health and Nutrition Examination Survey-I cohort study, which followed American men and women aged 25 to 74 for over a decade and randomised them to different combinations of 10 nutritional supplements over a five-year period, found that vitamin C intake was associated with a lower risk of coronary heart disease (CHD).

Nutraceuticals Used against Cancer

1. Curcumin (Diferuloyl-Methane) from Turmeric (Curcuma Longa)

One powerful nutraceutical for the treatment of cancer is curcumin. According to pre-clinical research, curcumin suppresses carcinogenesis in a variety of cancer types, including pancreatic, colorectal, prostate, gastric, and hepatic cancer. It also does this at every stage of the cancer's development, including angiogenesis, metastasis, and proliferation. When used in conjunction with chemotherapy and radiation therapy for the treatment of cancer, it is far more successful [36].

2. Ginger

Ginger is a proven nutraceutical that reduces the negative effects of chemotherapy and radiation because it is antimutagenic, antioxidant, and anti-inflammatory. These characteristics of ginger provide it useful radioprotective action. GinsenosideRf has been shown to assist cancer patients reduce their morphine dosages, and ginseng's polysaccharides can aid with the negative consequences of cancer treatment regimens, which have been shown to reduce the chance of cancer recurrence by 50% [37].

3. Genistein

Strong isoflavonegenisteine exhibits promising anti-carcinogenic qualities. Certain components only exhibit their anticancer effects at greater quantities that are unattainable by typical food consumption, according to in vitro studies. Because of this, it is challenging to have the intended impact at the tumour site, which makes us believe that the mechanism of administration is a crucial component that should be taken into account in in vivo research and clinical trials [38]. The non-toxicity of the natural ingredients is a crucial component in the formulation of a medication. However, it has been shown that several substances—genistein included—are more effective when given early in life.

4. Carotenoids

These pigments are present in many types of plants, algae, and bacteria that are involved in photosynthesis. Their tetra terpenoid structure is linear. These can be found in organic foods like fruits and vegetables. The most widely utilised dietary carotenoids include lutein, zeaxanthin, β -carotene, β -carotene, β -cryptoxanthin, and lycopene. These pigments are utilised for skin health, including photoprotection and anti-aging. It has been observed that probiotics and carotenoids reduce UV-induced skin damage and modify early skin indicators of UV impacts. A combination of beta-carotene, beta-carotene, and lutein supplements has been shown to be beneficial for photoprotection. Comparably, it has been observed that a combination of beta-carotene, lutein, and lycopene carotenoids protects against erythema. Studies on the photoprotective properties of vitamins C and E have shown that they are useful for maintaining skin health [39]. Hydrophilic in nature, vitamin C is often consumed in high quantities through a variety of food products, with the aim of preventing the development of nitrous oxide metabolites that cause cancer. It functions as a cofactor for the production of collagen fibres and prevents the fibroblasts'

manufacturing of elastin, which stops its buildup and is a major role in photodamaged skin. When combined with vitamin E, it functions in concert with its transformation process. Tocopherols, which are the major type of lipophilic antioxidant, include vitamin E. It inhibits polyunsaturated fatty acid lipid peroxidation by binding with peroxy radicals [40].

Regulation of nutraceuticals in India

The Food Safety and Standards Authority of India (FSSAI) now oversee the regulations governing nutraceuticals and health supplements. The regulatory rules for the approval of nutraceuticals in India were established by the FSSAI. On August 28, 2020, the FSSAI released a guideline note to help prevent misunderstandings between different types of nutraceuticals. It makes clear that the purpose of health supplements is to add one or more nutrients with established health benefits to a person's regular diet. Foods designated for special dietary use (FSDU) have undergone further processing or formulation to meet nutritional needs for certain conditions [41]. Foods designated for special medical purposes (FSMP) are meant to be fed to patients with digestive problems exclusively or in part. Nutraceuticals constitute naturally occurring substances that are separated, refined, and extracted from food or non-food sources.

When ingested, these substances offer physiological advantages and support the receivers' overall health. Nutraceuticals and health supplements are marketed to the healthy population above the age of two and five, respectively. The FSDU and FSMP, on the other hand, are only available to adults above the age of two who meet certain qualifications. The fourth article of the 21-chapter Food Safety and Standards Act (FSSA) of 2006 governs the manufacture, manufacturing, marketing, sale, distribution, and import of nutraceuticals, nutritional supplements, and different functional foods [42]. The Food and Drug Administration (FDA) regulated dietary supplements for a large amount of time in order to ensure their safety and that their labelling was truthful and not misleading. The FSSA was enacted by the Indian government in 2006 with the aim of integrating and optimising the several regulations pertaining to dietary supplements, fortified foods, and nutraceuticals.

The parliament enacted the FSSAI legislation in 2006, but it wasn't until 2008 that it was put into effect. On September 5, 2008, the Indian government provided guidance to the FSSAI's foundation as a leading administrative expert, with a chairperson and 22 members. 2011 saw the publication of the Food Safety and Standards (FSS) regulations by FSSAI. These regulations included food product standards, food business, food product licencing and registration, packaging and labelling practices, and additives used in food products. August 2011 saw the implementation of the FSS regulations [43].

Nutraceuticals, food/health supplements, foods with particular dietary objectives, medical reasons, and novel/functional foods were all covered by the 2015 FSS standards. The chemical makeup of the developed food, surface modification/surface chemistry, primary particle size, solubility, digestibility, amount of nanomaterial, if any,

in the food product, and specific claim, if applicable, should all be included in any claimed novel foods in accordance with these guidelines.

Food labelling, including nutrition labelling, was specified by the Nutrition Labelling and Education Act (NLEA) in 1990 using FDA criteria that were later revised by the "Food Safety and Standards (Packaging and Labelling) Regulation, 2011." More legal security and a more stable environment were made possible by this legislation. It encourages creativity and avoids unfair competition from those that make exaggerated or deceptive promises [44]. The rule does not require anybody to make unfavourable statements about the product if positive assertions are prohibited. 2018 saw the implementation of the Food Safety and Standards (Advertising and Claims) Regulations. Its primary purpose was to control the claims and marketing made about food items by owners of food businesses.

Key nutraceutical products and their application in India

For ages, people have utilised nutraceuticals. Their significance is emphasised in a number of chronic illnesses, including inflammatory bowel disease, type 2 diabetes, multiple enteropathies, and malabsorption disorders that result in malnutrition. Flaxseed oil, fish oil, vitamin B6, and vitamin B12 control steroidal production, regulate the menstrual cycle, and lower the risk of premature labour. Nutritional practices have a major impact on peripheral vascular disease, cerebrovascular disease, heart failure, hypertension, and coronary heart disease. By changing cellular metabolism, vitamin D, coenzyme Q10, folic acid, omega-3, and polyphenols may lessen artery disease. Onions are a vegetable, while apples, cherries, and grapes are a fruit that contain flavonoids [45]. Ginger is utilised to treat palpitations and hypertension because of its anti-inflammatory and antioxidant qualities. Vegetables that are green or yellow in colour and high in phytosterol lower the risk of heart disease by preventing the absorption of cholesterol. By reducing oxidative stress, nutraceuticals including beta-carotene, lutein, lycopene, curcumin, and turmeric may have a beneficial impact on some diseases like Parkinson's and Alzheimer's disease, which are neurodegenerative disorders. Research indicates that jujube can help individuals with Alzheimer's disease recall their memories. Numerous herbal remedies that contain Tulsi, Guduchi, and Amla have also been proved to help with memory and learning [45].

SWOT Analysis of Indian Nutraceuticals Industry

Strengths:

- **Rich Heritage of Ayurveda:**
India has a strong traditional system of medicine, particularly Ayurveda, which contributes to the development of herbal and Ayurvedic nutraceutical products.
- **Diverse Product Range:**
The industry offers a broad spectrum of nutraceutical products, including dietary supplements, functional

foods, and herbal supplements, catering to a wide range of consumer needs.

- **Growing Health Consciousness:**
Increasing awareness of health and wellness among consumers has led to a growing demand for nutraceutical products as people seek preventive healthcare solutions.
- **Natural and Organic Emphasis:**
The trend towards natural and organic products aligns well with the nutraceutical industry, as many products are derived from natural sources, promoting a clean and sustainable image.
- **Research and Development:**
The industry benefits from ongoing research and development efforts, leading to the creation of innovative formulations and products with health-promoting benefits.

Weaknesses:

- **Regulatory Framework:**
The regulatory framework for nutraceuticals in India is evolving, and there may be challenges in terms of standardization, labeling, and categorization of products.
- **Quality Control:**
 - Maintaining consistent quality across products can be a challenge, and there may be variations in the quality of ingredients used in different formulations.
- **Limited Consumer Awareness:**
 - Despite increasing awareness, there may still be a lack of comprehensive knowledge among consumers regarding the benefits, usage, and proper dosage of nutraceutical products [46].

Opportunities:

- **Global Market Expansion:**
The global demand for nutraceuticals is growing, providing an opportunity for Indian companies to expand their market reach and export products to a broader audience.
- **Innovation in Formulations:**
There is ample room for innovation in product formulations, including the development of novel delivery systems, enhanced bioavailability, and the incorporation of emerging ingredients.
- **Collaboration with Traditional Medicine:**
Collaborating with traditional medicine systems, such as Ayurveda, and integrating traditional ingredients into nutraceutical formulations can create unique products with cultural and health benefits.
- **E-commerce Growth:**

The surge in e-commerce platforms provides an opportunity for nutraceutical companies to reach a wider consumer base and offer products through online channels [47].

Threats:

- **Regulatory Changes:**
Evolving and stringent regulations in India or in major export markets can pose challenges for compliance and market access.
- **Competition from Pharmaceuticals:**
Traditional pharmaceutical companies entering the nutraceutical space can intensify competition and potentially impact the market share of specialized nutraceutical firms.
- **Supply Chain Disruptions:**
Vulnerability to disruptions in the supply chain, including sourcing of raw materials, can impact the production and availability of nutraceutical products.
- **Consumer Skepticism:**
Increasing consumer skepticism and concerns about the authenticity and effectiveness of nutraceutical products can affect consumer confidence and demand.

CONCLUSION:

In summary, the nutraceuticals industry has the potential to develop and involves both nutrition and medical treatment to provide comprehensive medical support. They may be used as nutritional supplements, to cure and prevent different forms of cancer, to prevent disorders including cardiovascular disease, and for other medical purposes. As a result, the nutraceutical companies have a thorough understanding of the possible benefits of nutrients for human health. Currently, it is believed that medications belong in the medical field. Conversely, nutrition is solely considered a product for leading a healthy lifestyle. As both individuals interact and complement one another, work is expected to be done in the upcoming years. Improved healthcare and health care advantages are brought about by the use of modern technologies, such as genetically modified food in the food sector and nutraceuticals based on nanotechnology. This has further expanded the growth of the nutraceuticals revenue market. Scientific research confirms that the enhanced safety and potential benefits of recently created nutraceutical products will encourage investments in more advanced technologies, including nutrigenomics, convergent approaches, diverse imaging technologies, and their uses in the development of nutrition and healthcare.

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