



Review Article

Nutraceuticals: Regulatory process across the world

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ABSTRACT

Nutraceuticals are the products isolated from foods that are generally sold in medicinal form. They are of particular interest to reduce the expensive and high-tech disease treatment approaches currently employed in developed countries. Nutraceuticals show increase in shift towards preventive therapies and increasing disposable income, favourable pricing environment growth in pharma retail chain and increase in healthcare spending is mainly responsible for increasing market for nutraceuticals, but lack of standardisation and awareness, high pricing, marketing and distribution are some challenges. Nutraceuticals are a clear example of advancement in biotechnological products with a disproportionate and inadequate input into generating quality scientific evidence to back or refute their validity. To achieve better quality of life people started eating more vegetables, fruits, dietary supplements, nutraceuticals, phyto therapeutic substances and other plant foods. With the advancements in the qualitative and quantitative determining parameters, the requisition of these products has been found to be amplified. Due to this, the nutraceutical market has become a million-dollar industry at a global level. Urbanization, market globalization and economic development have led to changes in diet and lifestyle. Development of better characterized and research proven products will help to enhance the customer confidence in nutraceutical and functional food products in global market.

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1. Introduction

Inappropriate dietary patterns such as increased consumption of energy dense high fat diets, particularly saturated fats and decreased physical activity resulting in decreased energy expenditure have contributed to chronic, age and lifestyle related diseases such as cardiovascular disease, type II diabetes, osteoporosis and malignancy.¹ It is not surprising that as the population ages, globally, and tries to cope with the burden of chronic disease, the demand for food related products for improved health has increased in parallel. From ancient times, Ayurveda and Chinese medicine have prompted food as medicine;

either as therapeutic or preventive intervention for certain diseases.

Nutraceutical means any non-toxic food component that has scientifically proven health benefits including prevention and treatment of disease. Products isolated or purified from food are sold in medicinal forms not usually associated with food. A nutraceutical has a physiological benefit that it provides protection against chronic diseases.² With recent advances in medical and nutrition sciences, natural products and health-promoting foods have received extensive attention from both health professionals and the public. New concepts have appeared with this trend, such as nutraceuticals, nutritional therapy, phytonutrients, and phyto-therapy.³ Consumers being frustrated with the expensive, high-tech, disease-treatment approach in the

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modern medicines are seeking complementary or alternative beneficial products and the red tape of managed care makes nutraceuticals particularly appealing “let food be the medicine and medicine be the food”, quoted by Hippocrates about 2,500 years ago is certainly the tenet of today.

Nutraceuticals are the emerging class of natural products that makes the line between food and drugs to fade. Although the use of nutraceuticals by people has a long history, recently scientifically supported nutritional and medical evidence has allowed nutraceutical to emerge as being potentially effective. The nutraceuticals of both plant and animal origin holds exciting opportunities for the food industries to create novel food products in future. The concept of “nutraceutical” arose first in the survey from U.K., Germany and France, where diet was rated higher by the consumers, than exercise or hereditary factors to achieve a good health. The term nutraceutical was coined from nutrition and pharmaceutical by Stephen De Felice, founder and chairman of the Foundation for Innovation in Medicine (FIM) Cranford, NJ in 1989.⁴ According to De Felice, nutraceutical can be defined as a food (or a part of food) that provides medical or health benefits, including the prevention and or treatment of a disease. Nutraceuticals are found in a mosaic of products emerging from (a) The food industry, (b) The herbal and dietary supplement market, (c) Pharmaceutical industry and (d) The newly emerged pharmaceutical/ agribusiness/ nutrition conglomerates. It may range from isolated nutrients, herbal products, dietary supplements and diet to genetically engineered designer foods and processed products such as cereals, soups, and beverages. The marketing and promotion of nutraceuticals has been financially lucrative for pharmaceutical and biotechnology companies and a thriving industry has risen on the premise the food bioactive substances has similar chronic disease modifying health effects when delivered in isolation as nutraceuticals, as when it is ingested as part of a food. The market share of nutraceuticals in various regions was depicted in Figure 1.

Three categories of claims are currently used on labels, for foods, and dietary supplements including nutraceuticals in most countries.⁵ Firstly, nutrient content claims, describe the percentage of a nutrient in a product relative to the daily value. Secondly structure/function claims express the effect of a dietary supplement on structure or function of the body and lastly the health claims describe the relationship between a foods or bioactive ingredient and reduction in disease risk. The key factors for driving growth:

1. Demographics
2. Psychographics⁶
3. Rising consumer interest in preventive health⁷
4. Demand for more convenient formats^{8,9}
5. Innovations in food manufacturing

2. Hottest Nutraceuticals Trends

The hottest nutraceuticals are foods and beverages that provide added health benefits while satisfying the growing demand for convenience and delivering excellent taste and texture. They also address the increasing desire for healthier alternatives to junk foods and sugary beverages.

E.g. Drinking broth from beef and chicken bones (bone broth), Plant proteins and dry beans, chickpeas and lentil (powered by plants), Yogurt with Probiotics and kale (maintaining digestive wellness), Turmeric, Longevinex (addressing age related conditions), Caffeine, Stevia, monk fruit, aloe, coconut water and Erythritol (energy drinks).^{10,11}

2.1. Classification of nutraceuticals

1. Traditional Nutraceuticals - This category consists of the food which does not undergo any manual changes. The components are natural and are having some potential which are actively involved in health benefits.¹²
2. Non-traditional Nutraceuticals - Boosting of nutritional content by addition of nutrients, dietary components for improvement of quality of nutrition comprise this category of nutraceuticals.¹³
3. Fortified Nutraceuticals - Fortification of food components add micronutrients, essential trace elements and vitamins to food for enhancing the effectiveness and nutritional value.
4. Recombinant Nutraceuticals - It involves the application of biotechnology and genetic engineering in the production of energy providing foods such as yoghurt and cheese or extraction of bioactive components by enzymatic or fermentation technology.
5. Potential and Established Nutraceuticals - Potential nutraceuticals hold an assurance of medicinal benefits. These nutraceuticals have become established medicines only after sufficient data demonstration and clinical testing for their efficacy and safety.¹⁴
6. Herbals - The herbs possessing medicinal values to be implemented in treatment and prevention of ailments are been included in the class. Botanical products may consist of fresh plant used or any part such as dried leaf, fruit, stem, seeds, roots, or concentrated extract.¹⁵
7. Phytochemicals - These are the chemical constituents of plants with distinct biological action. These are been reported to have active components which exerts their effects toward the metabolism and biochemical reactions in living beings and thus provide health benefits.¹⁶
8. Functional Foods - Functional foods are the source of absolutely necessary nutrients providing more than the quantities required for maintenance, growth, and development. The term is specially retained

for food components that carry the evidence to provide an advantageous factor for health beyond basic nutrition.¹⁷

9. Dietary Supplements and Dietary Fibres - A dietary supplement is a product which comprises a supplementary dietary ingredient added as a remedy to deficiencies or diseases. A dietary ingredient is one which enhances the food and its nutritional assessment. Vitamins and minerals as dietary supplements exist in multiple ingredients or single ingredient products in the market.¹⁸

10. Probiotics and Prebiotics - Probiotics category includes the live microbial food ingredients and their action includes adhesion to gastrointestinal tract at specific sites and their survival leads to elimination of pathogens.^{19,20} Prebiotics category includes a selectively fermented ingredients or fibre that promotes changes in gastrointestinal micro flora and its activity providing good effects to the health of host.

Many nutraceuticals are marketed using pseudo-scientific terms such as promotes brain function and mental clarity, cardiovascular health and healthy blood sugar levels, prevents the effects of premature aging, reduces oxidative damage and inflammation in the nervous system. The theory of food synergy is gaining popularity; in food all biological constituents are coordinated, in contrast to dietary supplements including nutraceuticals which may have potential to offset the balance.²¹ The health claims which are attributed to biologically active ingredients when taken in the form of nutraceuticals have often little or doubtful scientific foundation.²² The market share of nutraceuticals in global market in different years was depicted Figure 2.

2.2. Global market of nutraceuticals

Global nutraceuticals market size is expected to reach \$302,306 million by 2022 from \$184,092 million in 2015 with a CAGR of 7.04% from 2016 to 2022. Developing economies are oriented toward preventive health care; hence, the demand for nutraceutical product increases significantly. In future, functional food & beverages industries are anticipated to use antioxidants in excess. These are expected to contribute to the market growth. Disease risk reduction claims are not allowed for nutraceuticals. The regulatory acts and issues related to nutraceuticals was shown in Table 1.

2.3. Japan

Foods with nutrient function claims are not heavily regulated and simply must satisfy the standards for the minimum and maximum daily levels of twelve vitamins and five minerals. Foods for specified health uses (FOSHU) require pre-marketing approval and refer to products containing dietary ingredients that have reported beneficial

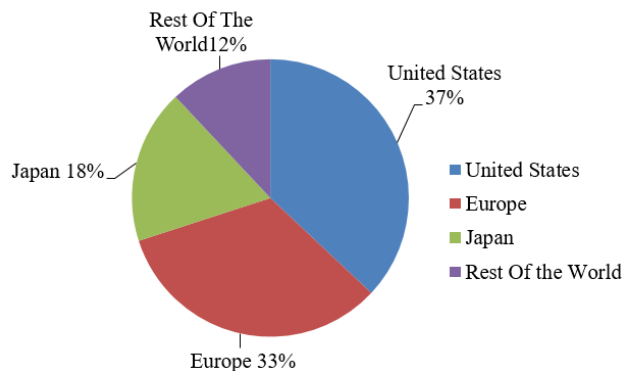


Fig. 1: Market share of nutraceuticals in various countries

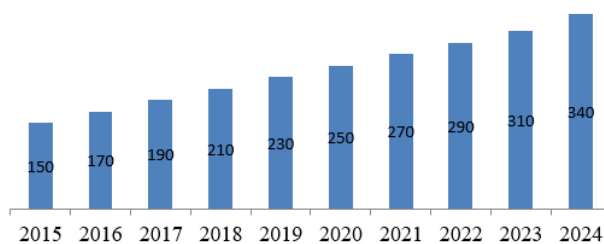


Fig. 2: Expected market size of nutraceuticals from 2015-2024 (US\$ Billion)

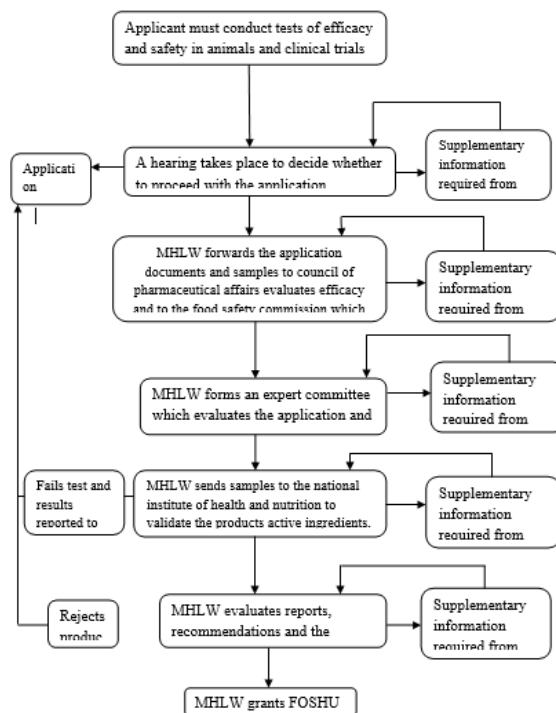


Fig. 3: Registration process of nutraceuticals in Japan

Table 1: Nutraceuticals related regulatory acts and issues in various countries

Country	Regulatory act	Regulatory issues	Companies
Japan	FOSHU (Food for Specified Health Use),1991	Focuses on health claims for specific products	Toyo Shinkayu Co., Ltd Yakult Honsha Co., Ltd Ajinomoto Co., Ltd Lotte Co., Ltd
	Foods with Health Claims (FHC),2001	Category of products expanded to include capsules and tablets	
	Foods with Nutrient Function claims (FNHC),2005	Restricted to the specified nutrients having nutritional functional claims in FHC	
Europe	Functional food science in Europe (FUFOSE),1996	Establish a science-based approach for concepts in functional food science	GSK, DANONE, Nestle Health Bayer Health Care Pharmaceuticals
	Regulation EC no.258/97,1997	Applies to GMP, foods and food ingredients	
	Regulation (EC)No. 1831/2003	For the authorization of Probiotics used as additives	
	Directive 2004/24/EC	Medicinal claims are made based on its traditional use of herbs	
	Regulation (EC) No 1924/2006	Establishes rules in labelling, presentation and the advertising of foods	
ROW	Regulation (EC)No. 353/2008	Establishes implementing rules for health claims in regulation (EC) No.1924/2006	Infinitus, Samilabs, Kingdomwaynutrition,INC.
	Regulation (EU) No 383/2010	Authorize food which reduces disease risk and children's health	
	State food and drug administration of china (SFDA),2003	Oversees and coordinate the health, food, and drug agencies.	
China	SFDA (State Food and Drug Administration, 2005	Guideline of registration for functional foods was promulgated.	Dabur, Himalaya
	State council legislative office (SCLO), 2009	Regulates foods that have a functional or health claim associated with their use.	
India	The food safety and standard act (FSSA), 2006	Manufacture, sell or import of novel foods, GMF, irradiated food, organic food, and food for special dietary uses, functional food, nutraceuticals and health supplements.	Dabur, Himalaya
	The food safety and standard authority of India (FSSAI), 2008	Single reference point for all matters relating to food safety and standards.	
	Food safety and standards rules and regulations, 2009	More emphasis on science based and participatory decisions.	
United States	The food safety and standard authority of India (FSSAI), 2010	Implemented	Amway, Mead Johnson Nutrition Coco Cola PepsiCo
	Nutrition labelling and education act (NLEA), 1990	Nutrition labelling of most foods regulated by the agency.	
	Dietary supplement health and education act (DSHEA), 1994	Describe the role of a nutrient or a dietary ingredient in the normal structure or function of the human body	
Brazil	Food and drug administration modernization act (FDAMA), 1997	Federal food, drug, and cosmetic act relating to the regulation to the regulation of food, drugs, devices, and biological products.	Tang, Yakult, Vitarella, Richester
	Food safety modernization act (FSMA), 2011	Ensure safe US food supply by preventing contamination.	
Canada	National Sanitary Surveillance Agency,ANVISA,2002	Check natural or synthetic substances having a demonstrated and physiologic activity	Nature Zen, Neptuen Wellness Solutions Nucro-Technics, Omega Nutrition Canada Inc
	Canadian Food and Drugs Act and regulation,1953	Presented the definition of food	
	Food Directorate of the Health Protection Branch of Health Canada,1996	Nutraceutical generally sold in medicinal forms not usually associated with food	
Australia and New Zealand	Canadian Food and Drugs Act,2001	Describe foods with health benefits beyond basic nutrition	Health life, Govita, Nutralife, Musashi
	Natural Health Product Directorate(NHPD),2003	Define nutraceutical	
	Food Standards Australia New Zealand(FSANZ),1991	Develops food standards to cover the food industry in Australia and New Zealand	
	Australian Capital Territory-Food Regulations Act,2002	Modification made in Food Act available in Parliamentary counsel	
	Queensland-Food Act,2006	Ensure food for sale is safe and suitable for human consumption	
	New South Wales Government-Food Regulation,2010	Regulation in food safety for food business	

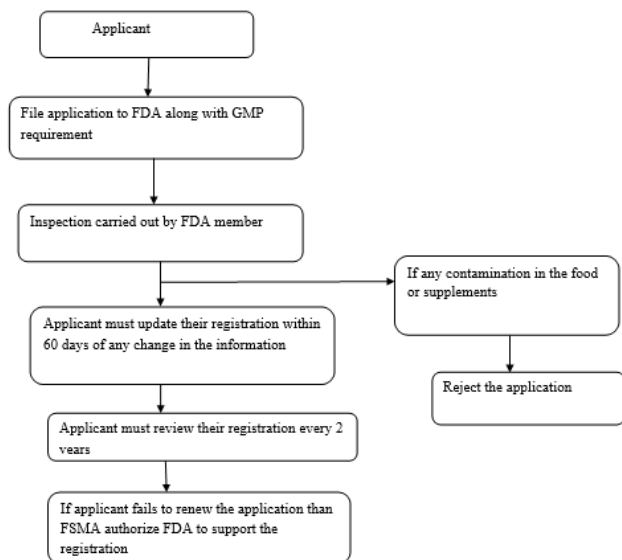


Fig. 4: Registration process of nutraceuticals in USA

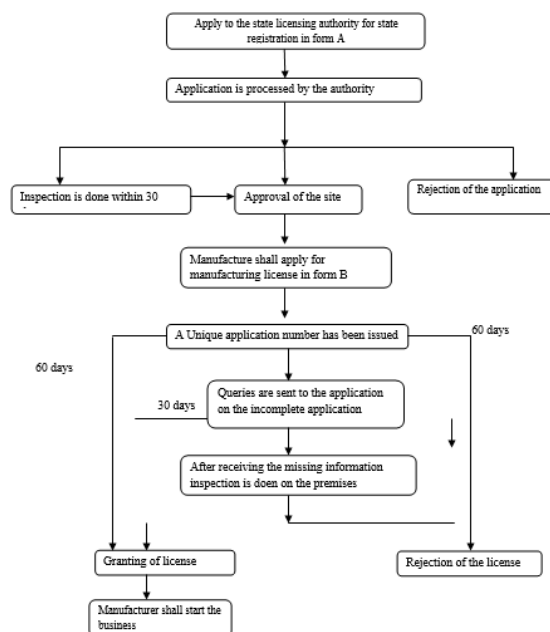


Fig. 6: Registration of nutraceuticals in India

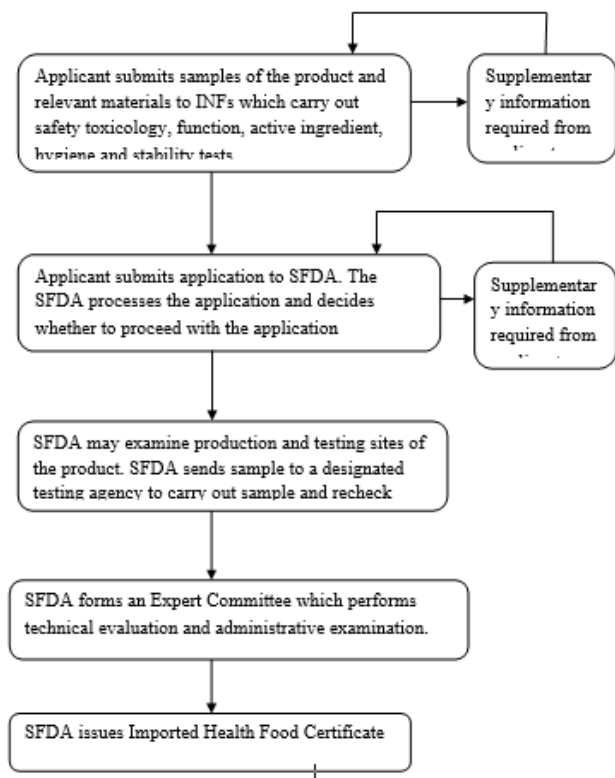


Fig. 5: Registration process of nutraceuticals in China

physiological effects and promote health.²³ Nutraceutical’s registration process in Japan was given in the Figure 3.

2.4. Europe

A complex range of regulations are applying to nutraceuticals in the EU, depending on the product type. These are mainly overseen by the European food safety authority (EFSA), which also evaluates claims and has a public register of nutrition and health claims. If a product is not on this certified list, it cannot be used until approved for inclusion following detailed scientific testing by the company and subsequent review by the EFSA. The EFSA also sets maximum and minimum levels of ingredients to be added to supplements. Labels cannot contain claims that their product will diagnose, cure, mitigate, treat or prevent a disease; nutrition and health claims must be authorised at an EU level. Between 2008 and 2011 the EFSA evaluated 2,758 food-related general health claims for their scientific evidence. Only around 10 percent of the claims could be substantiated. The European regulations on fortified foods were introduced in 2007, with permitted list of vitamins and minerals which are allowable in fortified foods. An economic impact on assessment commissioned by the European health claims alliance (EHCA) published in 2010 reveals concerns around the way in which the EHSA carried out assessments.²⁴

2.5. Registration of nutraceuticals in EU²⁵

All products labelled proprietary foods

a). Proprietary foods-not containing NF/FF/IF/FNS/GMF-or containing extracts or concentrates of botanicals, herbs, animal sources

1. Apply license with
2. List of ingredients and food additives in product
3. IFC category number
4. No ingredient approval required if as per 1(a)
5. Only approve food additive
6. Rs.25, 000 for 5 products which are significantly similar, difference being flavours or colours.
7. Product Approval and Screening Committee (PASC)

(b) Foods which are NF/FF/IF/FNS/GMF-or containing extracts or concentrates of botanicals, herbs, animal sources

2.6. Apply product approval

1. FBO to state section-22 category
2. Grant Provisional No Objection Certificate

Ingredient/food additive approval based on docs CODEX/JECFA/EFSA/FSANZ/other

2.7. Publish list

1. Send query to scientific panel/committee
2. Checklist on basis of approval
3. Inform FBO on action taken and specific information required.
4. Rs.25,000 for each product group of 5, which are significantly similar
5. Product Approval Screening Committee.

2.8. United states

Nutraceuticals mainly come under the category of vitamins and dietary supplements. A range of regulations are using, notably the dietary supplement Health and Education Act (DSHEA) from 1994, which covers dietary supplements, the federal food drug and cosmetic act, which covers all food and food additives, and good manufacturing practice regulations from 2007. The registration process of nutraceutical's in USA was shown Figure 4.²⁶ The driving factors for the nutraceutical market are;

1. Growing affluent middle-class populations with their increasing disposable incomes in developing countries
2. Women and senior citizens preferring a good digestive health
3. Physiological benefits of functional foods, which reduce the risk of chronic diseases related to cardiovascular problems and diabetes.
4. Lower R&D and regulatory burdens for pharmaceuticals in their nutraceuticals segment when compared to their prescription and OTC drugs.

With the increasing interest of nutraceuticals, dietary supplements, functional foods are related to growing awareness that the use of these not showing any undesirable side effects on the long-term use.²⁷

3. ROW (Rest of the World)

The registration process of nutraceuticals in China is tough process which requires more time and money. The registration process involves three main organizations. They are state food and drug administration (SFDA), which act as the in-charge of dietary supplements and registration; Ministry of health (MOH), which oversees the SFDA and the approval of new novel food ingredients and Administration of Quality Supervision Inspection and Quarantine (AQSIQ), which controls all imports and exports of nutraceuticals. The process of registration in China shown in Figure 5.²⁸

In India, the manufacture, storage, distribution, sale and import of nutraceuticals are regulated under the Food Safety and Standards Act (FSSA), the registration process is given in Figure 6.²⁹ The regulatory guidelines for manufacturing of nutraceuticals are less stringent than for pharmaceuticals, which may impact the Indian manufacturer's ability to produce nutraceuticals for export. In India, functional foods and beverages are expected to grow much higher when compared to dietary supplements over the next five years.³⁰ Intake of nutrients through food should be enough to prevent curative measures such as pharmaceuticals and traditional medicines being used in large quantities. In the absence of requisite nutrition through food, an external intervention in the form of health supplements and nutraceuticals has become imperative in India. In India, there is lack of investment and focus on research activities. There are 4 key demand drivers which have resulted in need for health supplements and nutraceuticals;

1. Malnutrition status in India and micro-nutrient deficiency.
2. Affordability: Increasing costs of hospitalization are driving consumers towards health supplements and nutraceuticals.
3. Affluence of working population with changing lifestyles and dietary patterns and increase in disposable income.
4. Awareness: Increasing concern about nutrition, awareness and access to information have led to an increase in use of health supplements and nutraceuticals.

4. Conclusion

Nutraceuticals are clear examples of advancement in biotechnological products with disproportionate and inadequate input into generating quality scientific evidence to back or refute their validity. Nevertheless, nutraceuticals

may well have potential in the future if backed by solid evidence especially for use under special circumstances, if not for regulate use. Until further evidence is available, health professionals should be alert to the possibility of adverse effects of nutraceuticals, the potential for harmful interactions with other medications and nutritional imbalances due to overdose. The most important point often missed is the indispensable value of the evidence-based health maintaining properties of the major components of an adequate diet. Nutraceuticals and other dietary supplements are generally more costly other than natural foods and greater benefits could be obtained at a lower cost from a healthy, balanced diet with food from all food groups. Nutraceuticals can provide substantial health benefits especially in the prevention and /or treatment of acute and chronic human diseases. But its development depends upon its quality, safety, long term adverse effects, and toxicity as well as supplementation studies and clinical trials in humans.

5. Source of Funding

None.

6. Conflict of Interest

None.

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