

NEUTRACEUTICALS AND HEALTH**Gharat K. B.*, Bokade A. S., Kasekar N. M. and Kadam V. J.**

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C.B.D., Navi Mumbai.**ABSTRACT**

The term nutraceuticals means NUTRITIVE+PHARMACEUTICAL. Nutraceutical is regarded as the bio active substance and the constituents are either of known therapeutic activity or are chemically defined substance generally accepted to contribute substantially to the therapeutic activity of the drug. Drugs show various side effects and adverse effects due to which consumers generally move to take food supplement to improve the health. This results in a worldwide nutraceuticals revolution. Nutraceuticals on the basis of their natural source, chemical groups categories into key terms -nutrients, herbals, dietary supplements, dietary fiber etc. The most rapidly growing

segments of the industry were dietary supplements (19.5 percent per year) and natural/herbal products (11.6 percent per year). Global nutraceutical market is estimated as USD 117 billion. In 2006 the Indian government passed Food Safety and Standard Act to regulate the nutraceutical industry. The principle reasons for the growth of the nutraceutical market worldwide are the current population and the health. The nutraceutical revolution will lead us into a new era of medicine and health, in which the food industry will become a research oriented one similar to the pharmaceutical industry. Nutraceutical market is seeing tidal growth mainly in United States, India and European countries. In contrast, a small number of these products have the potential to produce significant toxicity.

KEYWORDS: Nutraceutical, Nutrition, Dietary supplement, Global market, Revolution.**INTRODUCTION**

Nutraceuticals are oral dietary components naturally found in foods and believed to have a medical or health benefit. Nutraceutical is a term derived from "nutrition" and "pharmaceutics." The term is applied to those products which are isolated from herbal products, dietary supplements (nutrients), specific diets, and processed foods such as cereals,

soups and beverages that other than nutrition are also used as medicine. In the US, the term “nutraceutical” products are regulated as drugs, food ingredients and dietary supplements. The term is not defined the same in different countries, but is usually defined as a product isolated from foods that is generally sold in medicinal forms not usually associated with food.



Fig.No.1.

History

In 1932, KAL and Thompson were established as two of the first nutritional supplement providers in the United States. Over 80 years later, these two brands are part of our portfolio of more than 65 brands and 7,500 products serving families around the world in approximately 60 countries. The term nutraceuticals was coined from “nutrition” and “pharmaceutical” by Stephen Defelice MD, founder and chairman of the foundation for innovation in medicine (FIM) Cranford, New Jersey, in 1989.



According to Defelice “nutraceuticals are food or part of a food that provides medical or health benefits including the prevention and/or treatment of a disease.” Greek physician HIPPOCRATES (known as father of medicines) said “let food be your medicine” The philosophy behind is “focus on prevention” Other words used in the context are Dietary supplements, functional food, multi-functional food etc.

OBJECTIVEES

1. To develop and produce novel, nutraceuticals, functional food and techno-food products from indigenous sources to ameliorate nutrition and health issues.
2. To provide food quality analysis services to the private and public sectors, to evaluate food commodities /crop varieties for nutritive quality and consumer acceptance.
3. To develop partnership with food industry and carry out collaborative research in food sciences.
4. To impart trainings to small businesses / entrepreneurs for producing food products as cottage industry etc.

CLASSIFICATION OF NEUTRACEUTICALS

A. Traditional Nutraceuticals

- Chemical Constituents.
- Prebiotic Micro-organisms.
- Nutraceutical Enzymes.

B. Non-Traditional Nutraceuticals

- Fortified Nutraceuticals.
- Recombinant Nutraceuticals.

Traditional and Non-Traditional Nutraceuticals

Traditional Nutraceuticals	Non-Traditional Nutraceuticals
Traditional Nutraceuticals came in a medical format such as a capsule, tablet, or powder in a prescribed dose.	Modern Nutraceuticals are available as form of food, or included in foods or as whole food itself such as probiotic, drinks and yogurt.
e.g Vitamins And Minerals	e.g Food Supplement

Concepts of Nutraceuticals

In recent years however, as food composition has been scientifically proven to cause lifestyle related diseases, and has become a social issue. The nutraceutical products are recognized and produce health benefits like alleviating the risk of cancer and heart disease and also to prevent or treat hypertension, high cholesterol, excessive weight, osteoporosis, diabetes, arthritis, macular degeneration (leading to irreversible blindness), cataracts, menopausal symptoms, insomnia, diminished memory and concentration, digestive upsets and constipation, not to mention headaches; other products are touted as cures for thinning

hair, lack of confidence, poor complexion, varicose veins, alcoholism, depression, and lethargy.



Categories of Nutraceuticals

1. **Nutrient:** A feed constituent in a form and at a level that will help support the life of an animal. The main classes of nutrients are proteins, fats, carbohydrates, minerals and vitamins.
2. **Dietary Supplement:** A product that contains one or more of the following dietary ingredients: vitamin, mineral, herb or other botanical, amino acid (protein) and also includes the diet as concentrates, constituents, extracts or metabolites of these compounds.
3. **Neutraceutical:** Any nontoxic food component that has scientifically proven health benefits, including disease treatment and prevention.
4. **Herbals:** Herbs or botanical products as concentrates and extracts. Herbals are as old as human civilization and they provide a complete storehouse of remedies to cure acute and chronic diseases. India has the oldest written tradition for the nature's remedies called 'Auyrveda' which posses many effective means of ensuring health care. Numerous neutraceuticals are present in medicinal herbs as key components.

Advantages and Disadvantages of Nutraceuticals.

Advantages	Disadvantages
1. It enables us to derive daily dose of vitamins and minerals.	1. They are very costly.
2. They can contribute physical performance.	2. Taking supplements may increase risk of mega poisoning.
3. They are use for the treatment of various health condition.	3. Many food supplements interfere with absorption.

Manufacturing Process

Manufacturing process generally consists of the following:

- Sourcing ingredients for products.
- Quarantining and warehousing raw ingredients.
- Measuring ingredients for inclusion in products.
- Granulating, blending, grinding (chilsonating) the ingredients into a mixture with a homogeneous consistency.
- Encapsulating, tableting, pouring, pouching, bagging, or boxing the blended mixture into the appropriate dosage form using either automatic or semiautomatic equipments.

Applications of Nutraceuticals in Various Diseases.

Neutraceuticals	Diseases
1.Corn	Heart attack, Lung cancer
2 Dietary Polyphenols	Diabetes
3.Sorghum	Against Pathogen
4.Buck white	Obesity
4.Beta-Carotene	Cancer
5.Anti-oxidants: Vitamine E and C Ginkgo biloba: Huperzine alpha	Alzheimer's disease
6.Cod Liver Oil	Arthritis

Mechanism of Action

Number of nutrients have been classified as GRAS based upon documentation submitted by FDA. The GRAS designation allows an ingredient to be introduced as a food product ingredient. Some neutraceutical ingredients are marketed on the basis that they have been used for many years in the practice of traditional or cultural medicine. Several neutraceuticals can be listed as having more than one mechanism of action. Omega 3 PUFA, can be used as precursors for eicosanoid substances that locally vasodilate, brochodilate and deter platelet aggregation and clot formation. Also, they can reduce the activity of protein kinase C and tyrosine kinase both which are involved in cell growth signaling mechanism. Affecting cardiac hypertrophy and cancer. Also they inhibit the synthesis of fatty acid synthase, which is the principle enzyme in de novo synthesis of FA.

Growth of Nutraceuticals

Internationally, significant limitations to growth in this area are resulting from a necessity to properly label and assess the health effects of neutraceutical and functional foods. Selection for consistent production of high and low productivity of active plant components within

specific ecological regions will allow development of alternative nutraceuticals and functional foods with distinctive and more reliable health and food properties. The United States of America (USA) currently possesses the largest and most rapidly expanding functional food and nutraceutical market in the world India is the home of a large number of medicinal spices herbs and tree species that have a large domestic market. The functional foods and nutraceuticals are available as traditional Indian Ayurvedic Medicines in India and marketed in different brand names. No strict pharmaceutical regulations are available in India for the Ayurvedic and Nutraceutical health products. They are available to the public as over the counter without any medical prescription. India has a large share of the international functional food and nutraceutical market, and exports products to various countries. However, India's major export destination is the USA and Japan.

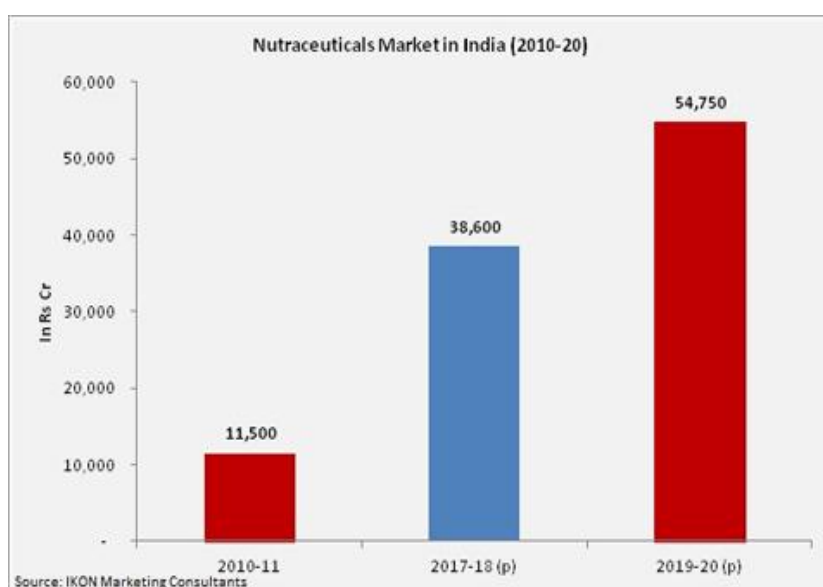
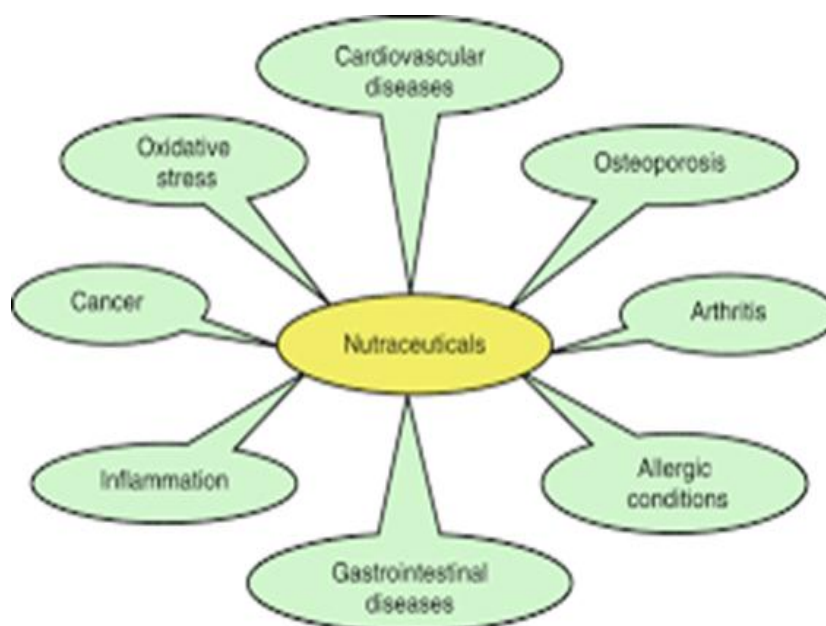


Fig. No. 3.

Areas Covered By Nutraceuticals

All therapeutic areas such as pain killers, cold and cough, sleeping disorders, digestion and also prevention of certain cancers, osteoporosis, blood pressure, cholesterol, depression and diabetes etc. have been covered by nutraceuticals.



1. Cardiovascular Diseases

Majority of the CVD are preventable and controllable. It was reported that low intake of fruits and vegetables is associated with a high mortality in cardiovascular disease. Many research studies have identified a protective role of a diet rich in fruits and vegetables against CVD. This apart, nutraceuticals in the form of antioxidants, dietary fibers, omega-3 polyunsaturated fatty acids (n-3 PUFAs), vitamins, and minerals are recommended together with physical exercise for prevention and treatment of CVD.

2. Cancer

Nutraceuticals may also be helpful in reducing toxicity, associated with chemotherapy and radiation therapy, and may lead to better life conditions by reducing cancer cachexia. The phytochemicals have shown different mechanism of actions at different cellular levels. Most of them have emerged as a versatile source of antioxidants affecting the signaling pathway related to redox mediated transcription factor.

3. Diabetes

Diabetes mellitus is characterized by abnormally high levels of blood glucose, either due to insufficient insulin production, or due to its ineffectiveness. The most common forms of diabetes are type 1 diabetes (5%), an autoimmune disorder, and type 2 diabetes (95%), which is associated with obesity. Nutraceuticals used: Lipoic Acid, Dietary fibers from psyllium, Minerals like magnesium, chromium, calcium etc. and vitamins like vitamin D improve insulin sensitivity, Extracts like cinnamon and bitter melon.

4. Nutraceuticals in stem cell therapy

Researchers found that some nutraceuticals have effect on growth of stem cell. Effect of Blueberry, green tea, catechin, carnosine, and vitamin D3 on proliferation with human bone marrow as compared with human granulocyte. There are indications for some beneficial effects of nutraceuticals such as antioxidant vitamins, essential amino acids, and polyunsaturated fatty acids in infant foods on the developing immune response. Actually mineral intakes such as Ca, P, Mg, Fe, Zn, I, F, and B, as well as vitamins D and K are important for the growth and development of bone and human nervous system.

5. Nutraceuticals in eye

Astaxanthin is an important naturally occurring carotenoid in the marine world such as sea bream, salmon, trout, and shrimps. It possesses a number of essential biological functions such as protecting against oxidation process, protecting against ultra violet light effects, immune response etc. Lutein is a carotenoid which is found in many vegetables and fruits including sweet potatoes, carrots, squash, tomatoes, mangoes, corn, and leafy greens such as kale and collards. Lutein and Zeaxanthin are used for the treatment of visual disorders.

Ayurveda and nutraceuticals

One cannot turn back the wheel of evolution, but taking the wisdom of traditional practices into account, Ayurvedic herbs can be developed as nutraceuticals for the management of NCDS. Also eggs enriched with Omega-3 fatty acids or curd enriched with lycopene can have more varieties by using carom (ajowan), or shunth (dry ginger), for the use of people suffering from Irritable Bowel Syndrome (IBS). Broadly, such advanced nutritional products based on Ayurveda principles may be aimed at providing for:

- i) Cellular health support,
- ii) Immune health support,
- iii) Bio-chemical/neuroendocrine support
- iv) Nutritional support, through phytonutrients.

Nutraceuticals and cosmetics

Cosmeceuticals are the products that applied topically. They contain certain ingredients that influence the biological function of the skin. Cosmeceuticals improve external appearance. Cosmeceuticals are growing very rapidly in natural personal care industry. Due to increase in global population this market is also increasing rapidly.

e.g Colgate Palmolive Products

Patents in nutraceuticals

1. Gilad & Gilad Granted U.S. Patent for Agmatine.
2. Natto Pharma Granted Canadian Patent for K2 and Omega-3s.
3. NattoPharma Expands U.S. Patent Application for MenaQ7.
4. Valensa Granted New Patents for 'Worry Free' Chia-Based Ingredients.

Different Indian Brands of Nutraceuticals**1. Prebiotic capsules**

Usage: Hospital, Clinical

Packaging Size: 10 X 10

Packaging Type: Blister

Product Type: Finished Product

Dose: As per prescription

Form: Capsules

Rs 850/Bo

2. Suboneyo Nutraceuticals High Protein Premix Powder

Form: Powder

Brand: Suboneyo

Protein (Dry basis): More than or Equal to 80%

Rs 200/ Kilogram

3. N-Source Energy Powder

Form: Powder

Packaging Size: 210 gm

Packaging Type: Pouch

Rs 39/ Pouch

Recent Advances In Nutraceuticals

FSSAI Issues New Directions On The Implementation Of Nutraceuticals Regulations 2016 Through directions issued on 31 December 2018 the FSSAI has clarified its decision regarding 14 ingredients listed under Appendix 1 of 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 (Nutraceutical Regulations).

In continuation of the directions issued previously in June and August 2018, the FSSAI has further decided on the following.

FBOs are allowed to continue to use the ingredient namely 'Vitamin D3' from lichen (*Cladonia rangiferina*) as a veg source in the existing products covered under the Nutraceutical Regulations, till such time the proposed amendment of the Nutraceutical Regulations are finalized and notified.

FBOs are directed to discontinue the use of ingredient namely Raspberry ketone, Silica, *Angelica Sinensis*, *Chlorella* growth factor, Chaga extract, Tea tree oil (*Melaleuca alternifolia*) in the products covered under Nutraceutical Regulations with immediate effect as no additional information has been provided by the applicant. No further manufacturing of products containing these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported under the aforesaid regulations before 29 June 2018 are allowed to be sold only up to a period of 30 days from the date of this direction.

FBOs are directed to discontinue the use of ingredients namely 'Oxalobacter Formigenes' in the products covered under the Nutraceutical Regulations with immediate effect since they exhibit properties of a drug and no further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported under the aforesaid regulations before 29 June 2018 are allowed to be sold only up to a period of 30 days from the date of this direction.

FBOs are directed to discontinue the use of ingredients namely *Paullinia cupana*(Gaurana), Saw Palmetto, *Notoginseng*, Pine bark extract from *Pinus radiata*, Pine bark extract from *Pinus pinaster* in the products covered under the Nutraceutical Regulations with immediate effect due to lack of adequate data such as history of safe usage in India for 15 years and also the specific advantage of these plants over the already listed India plants/ botanicals. No further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported under the aforesaid regulations before 29 June 2018 are allowed to be sold up to a period of 30 days from the date of this direction.

Based on the clarification provided by FBO that phytavail iron is mustard powder from *Brassica juncea*, which is already covered under Schedule IV of the Nutraceutical Regulations, it has been decided that no specific inclusion is required and the ingredient mustard powder can be continued to be used in products covered under the Nutraceutical Regulations subject to compliance with the aforementioned regulations.

Further, FBOs are allowed to continue the food business of existing formulations containing mere combinations of vitamins and minerals only up to one RDA in dosage formats such as tablets, capsules, and syrups for a period of three months from the date of this direction or till further orders whichever is earlier.

CONCLUSION

Currently, due to the lack of enough knowledge about usage, outcome, and safety of many nutraceuticals, phytonutrients as well as their corresponding therapies, many efforts have been put on these studied. The nutraceutical industry is growing at a rate far exceeding expansion in the food and pharmaceutical industries. In tomorrow's market, the most successful nutraceutical players are likely to be those companies in which functional product are just a part of a broad line of goods satisfying both conventional and health value point. Future demand of nutraceutical depends on consumer perception of the relationship between diet and disease.

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