



## Nutraceuticals: A review

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### ABSTRACT

Consumers are deeply concerned about how their health care is managed, administered and priced. They are frustrated with the expensive, high-tech disease treatment approach predominantly in modern medicine. Positioned at the interface between food and drugs, a growing body of products is assuming importance; the consumer is now looking for complementary or alternative beneficial products and that's why nowadays they are using nutraceuticals. Increasingly, they are using natural dietary supplements and other forms of nutraceuticals as part of a tremendous surge to have physiological benefits or to provide protection against diseases. Functional foods and nutraceutical products represent a value added growth opportunity both domestically and internationally. Development of better characterized and research proven products will help enhance consumer confidence in nutraceutical and functional food products in the world. This article briefly discusses about the basic information about the nutraceuticals and its importance.

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### Introduction

Industrialization has caused numerous air and water pollutions, soil and food contamination because of extensive use of various chemicals, heavy metals, electromagnetic waves, and other potentially harmful man-made items. These problems have led to an increased incidence of diabetes, obesity, different cancers and vascular diseases, physiological problems, as well as other degenerative diseases. The raised demands for health care have dramatically increased the cost of medical care. Therefore, people have tried to achieve a better quality of life by eating more vegetables, fruits, and other plant foods, taking dietary supplements or nutraceuticals, or using nutritional therapy or phytotherapy to replace chemotherapy or radiotherapy (1-3). Hence increasing demands for nutraceuticals, phytonutrients and their therapeutic services, manufacturers, marketers, and related licensed professionals have grown up accordingly.

Plants are one of the most important resources of human foods and medicines. Rapidly increasing knowledge on nutrition, medicine, and plant biotechnology has dramatically changed the concepts about food, health and agriculture, and brought in a revolution on them. 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 phytotherapy (4-6). These functional or medicinal foods and phytonutrients or phytomedicines play positive roles in enhancing health, and improving immune function to prevent specific diseases and also hold great promise to reduce side effects and health care cost (7).

Today we recognize the wisdom of the Greek physician Hippocrates's often-quoted saying, made nearly 2,500 years ago,

“Let food be thy medicine and medicine be thy food”. Referred to the functional foods, dietary supplements, and nutraceuticals, these products have been defined as “any substance that may be considered a food or part of a food and provides medical and health benefits including the prevention and treatment of disease. Perhaps the most descriptive term used to refer to this part food/part drug products is “nutraceuticals”. This name was coined by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine, located in Cranford, New Jersey (8).

The term “nutraceutical” combines the word “nutrient” (a nourishing food or food component) with “pharmaceutical” (a medical drug). Nutraceuticals may contain substances that are “natural” expressed intent of treatment or prevention of disease but may not be generally recognized as safe (9).

#### Categories of nutraceuticals

Nutraceuticals are non-specific biological therapies used to promote wellness, prevent malignant processes and control symptoms.

These can be grouped into the following categories (10):

**Nutrient:** A feed constituent in a form and at a level that will help support the life of an animal. The chief classes of feed nutrients are proteins, fats, carbohydrates, minerals and vitamins.

**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.

**Nutraceutical:** Any nontoxic food component that has scientifically proven health benefits, including disease treatment and prevention.

**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 nutraceuticals are present in medicinal herbs of key components.

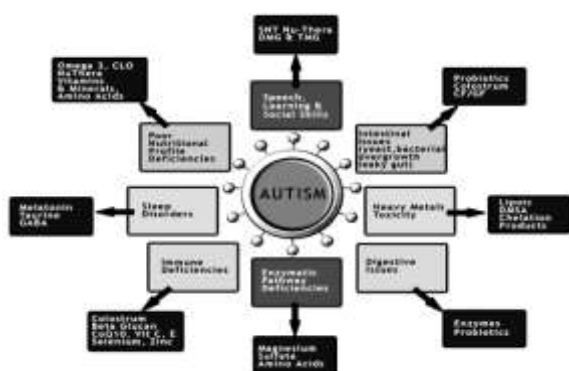
#### What are functional foods and nutraceuticals?

The concepts of nutraceuticals, functional or medical foods, or dietary supplements are confusing and most often they can be used interchangeably. These concepts may be distinguished by their description from different points of view, e.g. functional food is a more general term to emphasize foods with specific or strong purposes (11). Dietary supplements have more defined health roles such as vitamins, minerals, herbs or other botanicals, amino acids, and other dietary substances intended to supplement the diet by increasing the total dietary intake of these ingredients (12). Dietary supplements are not intended to treat or cure disease (13), whereas nutraceuticals more emphasize the expected results of these products, such as prevention or treatment of diseases.

However, functional food concept is different from nutraceuticals and can be defined as food products to be taken as part of the usual diet in order to have beneficial effects that go beyond what are known as traditional nutritional effects (14).

Functional food products are milk, cheese and eggs that are all enriched with omega-3 fatty acids; yogurt enhanced with live active cultures (probiotics); fruit juices and drinks with increased antioxidant levels; cereals and grains such as wheat, oat, barley and fenugreek products with enhanced amounts of dietary fibre; modified fatty acid vegetable oils; and vegetable proteins from soy, canola and hemp, legumes and fruit products (15,16)

Nutraceuticals are described as products extracted, purified or produced from a plant, animal or marine source (e.g. antioxidants from blueberries, elk velvet, fish oils), or produced from dried, powdered, or pressed plant material and demonstrated to have a physiological benefit, or to provide protection against chronic disease (17), applications of functional foods and nutraceuticals are shown in Figure 1.



**Figure 1: Applications of functional foods and nutraceuticals**

#### Why Nutraceuticals?

➤ For so many of us, it is impossible to get adequate nutrition from the routine food.

➤ Secondly, we live in highly toxic environment, filled with pollution and pesticides that throw off our body's ability to regulate it.

➤ Also, consider the number of new ailments that are haunting us: chronic fatigue, Epstein Barr, lupus etc. now they are wide spread in our population.

➤ This is more sensible strategy-to strengthen our system or terrain rather than settling for antibiotic which has lost their effectiveness.

➤ There are typically side effects from drugs because they are not natural to the body, whereas with good quality supplementation that can be absorbed and utilized by the body, we can truly strength our body and add vitality.

#### Why Nutraceutical seems attractive?

➤ Many diets are rich in phenolics component and are daily consumed by human beings.

➤ They rarely have any side effects.

➤ They have relatively long half-life

➤ They can be easily absorbed in the intestine after ingestion.

➤ They do not require on appointment with a health care provider and are easily available without prescription.

➤ Many people believe this approach is more natural than using prescription drug. They feel dietary supplements will help them feel stronger and healthier, give them more energy and prevent illness.

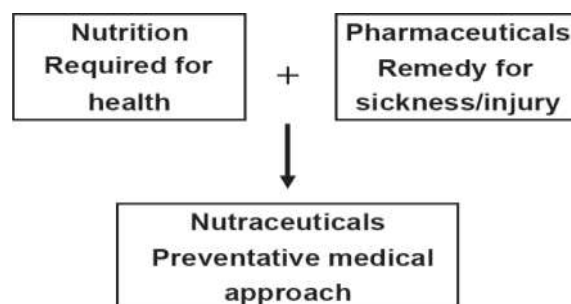
➤ Some people turn to these products when they feel standard treatments for their specific illnesses have failed.

#### Concept of nutraceuticals

In the pharmaceutical development process, it is a requirement to have clinical test results from animal tests and studies, for verification of their therapeutic effects. But in the case of nutrition, there was no verification method for foods in preventing diseases in the past. In recent years however, as food composition has been scientifically proven to cause life style-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.

The concept of Nutraceuticals has started to be acknowledged as one of the measures for preventing such diseases (18-24), the concept of nutraceuticals is shown in figure 2.



**Figure 2. Concept of Nutraceuticals**

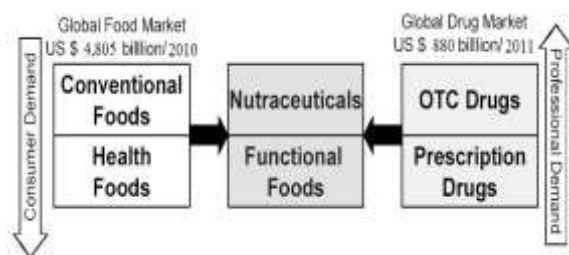
#### Nutraceutical Growth

In the global marketplace nutraceuticals and functional foods have become a multi-billion dollar industry and estimates. Internationally, significant limitations to growth in this area are resulting from a necessity to properly label and assess the health effects of nutraceutical 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 (25).

India is the home of a large number of medicinal herbs, spices and tree species that have a substantially large domestic market. The functional foods and nutraceuticals are available as traditional Indian Ayurvedic Medicines in India and marketed in different brand names. However, no strict pharmaceutical regulations are available for the Ayurvedic and nutraceutical health products in India; 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 (26), the global food market growth about the nutraceuticals is shown in figure 3.



**Figure 3: Global food market growth about the nutraceuticals**

Different scientific groups as well as various government agencies (27-40) increased the popularity of nutraceuticals and functional foods among the public sector.

- An Increase in Public Health Consciousness,
- An Aging Population,
- Escalating Health Care Costs,
- Recent Advances in Research and Technology,
- Changes in Government Regulations and Accountability,
- Expansion of the Global Marketplace,
- A Sympathetic Media,
- Science-based Evidence is contributing to the Popularity of Functional Foods.

Recognition of variation in functional food and nutraceutical composition will provide opportunity for the industry to give consumers a variety of new products that can be developed for specialized markets.

#### **Dietary Supplement Health and Education Act**

Dietary Supplement Health and Education Act (DSHEA) passed in 1994 to govern the human nutraceutical market which does not permit FDA to consider a new product a "drug" or "food additive" if it falls under the definition of a "dietary supplement," which includes among other substances any possible component of the diet as well as concentrates, constituents, extracts or metabolites of these components (9).

With the passage of the Dietary Supplement Health and Education Act of 1994, the definition of nutraceuticals has been expanded to include vitamins, minerals, herbs and other botanicals, amino acids, and any dietary substance for use by humans to supplement the diet by increasing total dietary intake. To comply with the regulations, a nutraceutical must be labeled as a "dietary supplement" and shall not be represented for use as a conventional food or as a sole item of a meal or diet

#### **FDA Modernization Act**

The passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA) made additional options

available to the manufacturers of nutraceuticals leads to brings a balance in FDA regulations between approving therapeutic products so that they can benefit patients and protecting public health with significant changes were also made in the labeling of nutraceuticals (41).

#### **Global demand in Nutraceutical**

World demand for nutraceutical ingredients advanced 5.8 percent annually to \$15.5 billion in 2010, serving a \$197 billion global nutritional product industry. China and India will emerge as the fastest expanding nutraceutical markets as strong economic growth allows them to upgrade and diversify food, beverage and drug production capabilities.

Herbal, non-herbal extracts has increasing acceptance by consumers and medical professionals pushed world demand for herbal and non-herbal extracts up to 6.5 percent annually to \$1.85 billion in 2010.

Nutrients, minerals and vitamins demand reached \$9.5 billion in 2010, up to 6.3 percent annually from 2005. Global demand for nutraceutical vitamin ingredients increased up to 4.6 percent annually to \$4.2 billion in 2010. Natural vitamin E formulations and beta carotene (vitamin A) will also fare well in the global marketplace based on efficacy advantages over synthetic ingredients for adult and pediatric nutritionals (42, 43).

#### **Traditional vs. Nontraditional**

Nutraceuticals on the market today consist of both traditional foods and nontraditional foods. Traditional nutraceuticals are simply natural, whole foods with new information about their potential health qualities. Many if not most fruits, vegetables, grains, fish, dairy and meat products contain several natural components that deliver benefits beyond basic nutrition, such as lycopene in tomatoes, omega-3 fatty acids in salmon or saponins in soy. Even tea and chocolate have been noted in some studies to contain health-benefiting attributes. Nontraditional nutraceuticals, on the other hand, are foods resulting from agricultural breeding or added nutrients and/or ingredients (44).

#### **Characterization of Nutraceuticals**

The concept of functional foods is susceptible of different interpretations that referred to their characteristics, their active components, or their regulatory framework (45-49). Functional foods are consumed by public but they may not aware about their specific components; however, they are recognized because they "are good for health".

These "nutraceuticals" are widely used in holistic treatments for a variety of therapies, but they are available in the market without prescriptions due to unavailability of strict regulated pharmaceutical industry. Nutraceutical suppliers must monitor the variations in raw materials and finished products to ensure the quality and safety of the product. The FDA must establish Good Manufacturing Practices for nutraceuticals to regulate the Pharmaceutical Industries to ensure the quality of the products (50).

#### **Current Research in Nutraceuticals**

A great deal of current research is focused on traditional herbal extracts. Investigators are examining claims linking these extracts with health enhancement and prevention of chronic diseases. At least in part, this represents an effort to legitimize homeopathic remedies and Eastern medicine. Additionally, it seeks to provide patients and physicians with much-needed safety and efficacy data.

The explosive demand growth for bioactive ingredients for nutraceuticals and functional foods is being driven by frequently cited health concerns:

- Cardiovascular disease
- Breast, skin, colorectal, and brain cancers
- Female health concerns
- CNS disorders
- Metabolism management
- Gastrointestinal disorders
- Immuno modulation

A significant problem with the use of nutraceuticals in treating diseases is the lack of serious studies published with clear clinical evidence. The development, production, packaging, marketing, and sales of nutraceuticals has come a long way and is evolving constantly. Nutraceuticals are the preferred choice of today's consumer for regular usage. The latest scientific research and clinical trials continue to boost and add impetus to this industry (51).

#### **Safety and Efficacy**

In nutraceutical products some substances due to direct toxic effects it may cause some problems. Safety of a nutraceutical product is often easier to establish than efficacy. Many nutraceuticals products have been used as alternatives for both nutrition and medicine. Many manufacturers make illegal claims without proper data to support their products safety and efficacy. As such, consumers need assurance that a product is safe and hopefully able to do what it says it does. Above anything else, nutraceuticals should be safe (52).

#### **Labeling and Claims in Nutraceuticals**

Labeling, and strict control over formulations and branding are still not required for most products. Health claims on nutraceuticals serve to alert consumers as part of an overall healthy diet, which may reduce the risk of certain diseases. The FDA initially authorized seven health claims in 1993 as part of the 1990 Nutrition Labeling and Education Act (NLEA). Since 1993, the FDA has authorized six more claims. In an effort to accelerate this information to consumers, the Food and Drug Administration Modernization Act of 1997 included a provision intended to speed up the process that establishes the scientific basis for health claims.

Although food manufacturers may use health claims to market their products, leads to benefit consumers by providing information on healthful eating patterns that may help reduce the risk of heart disease, cancer, osteoporosis, high blood pressure, dental cavities or certain birth defects. Health claims are different from structure/function claims, which also may appear on conventional food or dietary supplement labels. Unlike health claims, structure/function claims don't deal with disease-risk reduction. Also, the FDA does not pre-approve or authorize structure/function claims. Rather, when the manufacturer uses a structure/function claim, the company is responsible for making sure the claim is truthful and not misleading.

Many academic, scientific and regulatory organizations are considering ways to establish the scientific basis to support claims (other than health claims) for the functional components of nutraceuticals. These are the five types of health-related statements allowed on food and dietary supplement labels:

- Nutrient-content claims indicate the presence of a specific nutrient at a certain level.
- Structure and function claims describe the effect of dietary components on the normal structure or function of the body.

➤ Dietary-guidance claims describe the health benefits of broad categories of foods.

➤ Qualified health claims convey a developing relationship between components in the diet and risk of disease, as approved by the FDA and supported by the weight of credible scientific evidence available.

➤ Health claims confirm a relationship between components in the diet and risk of disease or health condition, as approved by FDA and supported by significant scientific agreement (52).

#### **Regulations**

Nutraceuticals have no official meaning and do not constitute a distinct category of foods; simply they are natural, consumers have been eating whole foods for thousands of years. As a result, the FDA regulates them in the same way they regulate all foods: The safety of ingredients must be assured in advance, and all claims must be substantiated, truthful and non-misleading (52).

The governmental administration of food and drugs in many countries such as the United States of America, Canada, European Union, China, and India have strict regulations on food and drugs in terms of manufacturing, servicing, marketing, and usage, but not having a complete regulation. Many countries are making corresponding laws, or complementary regulations, or addressing issues with new explanations. The more detailed regulations on nutraceuticals, phytonutriton or phytotherapy, or nutritional therapy are being worked out through consultations with expert panels that can provide descriptions of regulatory hurdles for these products and practices, Good Manufacturing Practice (GMP) compliance, generally recognized as safe (GRAS) status, analytical methods and validation (53-58).

#### **Indian Regulatory aspects of Nutraceuticals (59-60)**

The regulatory framework of nutraceuticals in India needs attention from the relevant authorities. Globally, the regulatory authorities are aware of changing needs of consumers and proactively protect consumers by amending existing laws to accommodate changes but in India old laws such as Prevention of Food adulteration Act, 1954, which regulates packaged foods, still exist for manufacturers. In addition, they need to tolerate by many other cumbersome laws such as:

- Standards of Weights and Measures Act, 1976, and the Standards of Weights and Measures
- (Packaged Commodities) Rules, 1977 (SWMA)
- Infant Milk Substitutes, Feeding bottles and infant foods (regulation of production, Supply and Distribution) Act, 1992 with Rules, 1993 (IMS)
- Edible Oils Packaging (Regulations) Order, 1998
- Fruit Products Order 1955 (FPO)
- Meat product Order 1973
- Milk and Milk Products Order 1992
- Vegetable Oils Products (Regulation) Order 1998 (VOP)
- Atomic Energy Act, 1962 and Atomic Energy (Control or irradiation of Food) Rules 1996
- Consumer Protection Act 1986 and the Consumer Protection (Amendment) Act, 2002 and Rules 1987
- Environment Protection Act, 1986 and Rules 1986
- Agricultural Produce (Grading and Marking) Act, 1937 (as amended up to 1986) and 49
- General Grading and Marking Rules 1986 and 1988 (AG Mark)
- Bureau of Indian Standards (BIS) Act 1986

### Future issues and proposals

Change in the lifestyle can prevent the diseases like metabolic syndromes. One of the solutions in the lifestyle change is changes in their diet. The key issues for Nutraceuticals are

- Establishment of scientific assessment standard for prevention of diseases
- Establishment of assessment system for disease prevention by human trials
- Establishment of seamless system to transfer stage from basic research to industrialization.

Nutraceuticals are not necessarily a single material; therefore the expected effect for the prevention of disease might be the complex action of several components which are present in the product, it is also necessary to compare preventative effects for different types of food. Hence, it is necessary to conduct biomarker research for prevention of target diseases. Therefore, it is also necessary to define the measurement method of biomarkers and standardize indicators (61).

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