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Nutraceutical Market and its Regulation

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ABSTRACT

The definition of nutraceutical that appears in the latest edition of the Merriam-Webster Dictionary is as follows: A food stuff (as a fortified food or a dietary supplement) that provides health benefits. If indeed a claim was made that implied medicinal benefit regarding a nutraceutical product, the product would be required to comply with the regulatory requirements for medicinal products, in respect of safety, efficacy and quality testing and marketing authorisation procedures. Global market for nutraceuticals is growing day by day and it is expected to reach \$176.7 billion in 2013, a compound annual growth rate (CAGR) of 7.4%.

Key words: Nutraceuticals, market demand, regulatory frame work

INTRODUCTION

The term nutraceutical was coined from nutrition and pharmaceutical in 1989 by Stephen DeFelice, MD, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ. According to WHO, about three-quarters of the world population depends upon traditional remedies for the health care of its people. In fact, herbs and nutraceuticals are the friends of human being. They not only provided the food and shelter but also serve the humanity to cure different dysfunctions (Ansari and Inamdar, 2010). According to De Felice, nutraceutical can be defined as, a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a dis-ease (Brower, 1998). However, the term nutraceutical as commonly used in marketing has no regulatory definition (Zeisel, 1999). Since the term was coined by Dr. DeFelice, it's meaning has been modified by Health Canada which defines nutraceutical as: a product isolated or purified from foods and generally sold in medicinal forms not usually associated with food and demonstrated to have a physiological benefit or provide protection against chronic disease. Examples: beta-carotene, lycopene. The definition of nutraceutical that appears in the latest edition of the Merriam-Webster Dictionary is as follows: A food stuff (as a fortified food or a dietary supplement) that provides health benefits. However, with all of the aforementioned positive points, nutraceuticals still need support of an extensive scientific study to prove their effects with reduced side effects (Wildman, 2001; Whitman, 2001; Heyland, 2001). This can be achieved by the enactment of FIM proposed Nutraceutical Research and Education Act (NREA) (Conover, 2002).

EXAMPLES OF NUTRACEUTICALS CURRENTLY ON THE MARKET

Fortified cereals: Various breakfast cereals contain added vitamins and minerals (iron, zinc, vitamin B12 and folic acid).

Vitamin and mineral supplements: Either sold as separate supplements or as a mixture with varying amounts of the different compounds.

Additional supplements: Supplements other than vitamins and minerals which are believed to have beneficial effect on health (cod liver oil, primrose oil, glucosamine, garlic, echinacea and ginkgo biloba).

Energy drinks and tablets: Drinks contain stimulants such as caffeine and sugars or isotonic drinks containing sugars and salts to mimic the solute potential of the cytosol and thus create a solution which is osmotically balanced with the body.

Foods to reduce cholesterol levels: The most common example of which is Benecol™ a margarine and possibly in the future a whole range of foods which will contain Abcor™ a compound developed by Nutri-pharma and claimed to reduce cholesterol by 15-20% in four months.

Pro-biotics: Foods containing bacteria that are believed to improve health e.g., Yakult™ (with 6.5 million friendly bacteria in every drink) which contains lactobacillus casei shirota, a bacteria which is thought to improve gut health, incidence of heart disease and certain cancers.

REGULATION

Unlike pharmaceutical drugs, within the United States, nutraceutical products are widely available and monitored with the same of scrutiny as dietary supplements. Within the oversight of the Federal Food and Drug Administration, unlike many other countries such as Canada, the use of broad-based definitions creates inconsistent credibility distinguishing the standards, function and effectiveness between nutraceuticals and dietary supplements. Within this loose regulatory oversight, legitimate companies producing nutraceuticals provide credible scientific research to substantiate their manufacturing standards, products and consumer benefits and differentiate their products from dietary supplements.

Despite the international movement within the industry, professional organizations, academia and health regulatory agencies to add specific legal and scientific criterion to the definition and standards for nutraceuticals, within the United States the term is not regulated by FDA. The FDA still uses a blanket term of dietary supplement for all substances without distinguishing their efficacy, manufacturing process, supporting scientific research and enhanced health benefits.

In 2005, Institute of Medicine (2005) created a blue-ribbon committee to create an improved framework for the Federal Food and Drug Administration to evaluate dietary supplements. Though the improved framework fails to distinguish between nutraceuticals and dietary supplements. With the continued use of a broad definition and lacking greater distinction, a cost-effective and scientifically based framework was required to evaluate the safety of dietary supplements including those consumer products recognized internationally as nutraceuticals.

CURRENT REGULATORY FRAMEWORK

Although the name implies that nutraceuticals have medicinal properties they are in fact food types. Because of this, claims regarding the beneficial effects of nutraceuticals can only be health claims and not medicinal claims. For instance the claims must not state that by eating/taking the nutraceutical a disease will be prevented or cured but only that it may help to improve health, possibly supporting in the avoidance of the onset of illness.

If indeed a claim was made that implied medicinal benefit regarding a nutraceutical product, the product will be required to comply with the regulatory requirements for medicinal products, in respect of safety, efficacy and quality testing and marketing authorisation procedures.

As it stands nutraceuticals are required to comply with food law. The Food Safety Act 1990 (FSA), subsequent primary and secondary legislation and codes of practice ensure that food placed on the market is safe and that any information provided about the product is not misleading.

FOOD REGULATION IN INDIA

India is the largest producer and consumer of tea and world's second largest producers of fruits and vegetables but only a small amount of perishable agriculture products are processed approximately 2% in comparison of 80% in US.⁵ Barriers to growth on food sector include poor infrastructure and logistic and tight food regulation. The wide range of food regulation policy makers and enforcement agencies prevailing in different sectors of food industry contributed to considerable confusion among the consumers, producers and retailers and business and such a detrimental to growth of functional food and nutraceutical industry. By the mid 1990s the food processing sectors laws framed in a veritable grid of regulation including a multitude of states law as well as following national laws:

- Export (Quality Control and Inspection) Act 1963
- Solvent Extracted Oil Control (SEO) Order 1967
- The Insecticide Act 1968
- Meat Food Products Order MFPO 1973

Prevention of Food Adulteration Act (PFA) 1954 rules (ministry of health and family welfare and family welfare) with last amendments in 1986:

- Bureau of Indian Standards Act 1986
- Environmental Protection Act 1986
- Pollution Control Act 1986
- Milk and Milk Products Order 1992
- The Infant Milk substitutes feeding bottles and infants food (regulation of production, supply) Act 1992 and Rules 1993
- Food Product Order FPO 1995
- Agriculture Produce Act
- Essential Commodities Act 1995 (Ministry of Food and Consumers Affairs)
- Industrial license
- Vegetable Oil Product Control (VOP) order 1998

In 1998 Prime Minister's council on trade and industry appointed a subjective group on food and agriculture industries which recommends a unified legislation under a single food regulatory authority. Special consideration was given on nutraceutical and functional food-a poorly defined segment with growing potential and implications on health of consumers.

In 2002, a National nonprofit Association had been constituted with main objectives that every food manufacturing company should provide scientific based support to their products in 2003, a Ministry of Health expert report indicated to need under food laws, to create new categories for regulating functional food and dietary supplements.

In 2005, a number of committee, including the standing committees of parliament on agriculture submitted its 12th report in which the need for a single regulatory body and integrated law has emphasized. Finally Indian food safety standard bill 2005 signed into law.

The Indian Food Safety and Standard Act came into enforcement in 2006 with the two main objectives:

- To introduce a single statute relating to food and
- To provide for scientific development of the food processing industry.

MARKET AND DEMAND

About two-thirds of the American population takes at least one type of nutraceutical health product. The use of nutraceuticals, as an attempt to accomplish desirable therapeutic outcomes with reduced side effects, as compared with other therapeutic agents has met with great monetary success. The preference for the discovery and production of nutraceuticals over pharmaceuticals is clearly seen in pharmaceutical and biotech companies. Some of the pharmaceutical and biotech companies, which commit major resources to the discovery of nutraceuticals include Monsanto (St. Louis, MO), American Home Products (Madison, NJ), Dupont (Wilmington, DE), Abbott Laboratories (Abbott Park, IL), Warner-Lambert (Morris Plains, NJ), Johnson and Johnson (New Brunswick, NJ), Novartis (Basel, Switzerland), Metabolex (Hayward, CA), Genzyme Transgenic, PPL Therapeutics and Interneuron (Lexington, KY). The nutraceutical industry in the US is about \$86 billion. This figure is slightly higher in Europe and in Japan; represents approximately a quarter of their \$6 billion total annual food sales- 47% of the Japanese population consume nutraceuticals. Even without specific financial figures, business reports continually suggest that the market is consistently growing (Kalra, 2003).

One possible explanation for the growth of nutraceuticals in the United States is the aging baby-boomer population. As the average age of the citizens continues to rise, the population increases its focus on health and wellness. By halfway through the 21st century, there could be almost 142 million Americans over the age of 50, based on a projected population of nearly 400 million citizens.

Although the price of some nutraceuticals may drop as generic products make their way into the market, people's dependence on these products and their increasing availability suggests that the growth of the market shall remain stable.

GLOBAL NUTRACEUTICAL MARKETS

According to a new technical market research report, Nutraceuticals: global markets and processing technologies (FOD013C) from BCC Research, the global market for nutraceuticals was worth \$117.3 billion in 2007. This is expected to reach \$176.7 billion in 2013, a compound annual growth rate (CAGR) of 7.4%.

The market is broken down into nutraceutical foods, beverages and supplements. Nutraceutical foods were the largest market segment in 2007, worth \$39.9 billion. This is expected to increase \$56.7 billion in 2013, for a CAGR of 6.9%.

Nutraceutical supplements have the second largest market share, generating \$39.0 billion in 2007. This segment should reach \$48.8 billion in 2013, for a CAGR of 3.8%.

The nutraceutical beverages segment represents the fastest growing segment and is expected to have the largest share of the market by 2013. This segment was worth \$38.4 billion in 2007 and is expected to increase to and \$71.3 billion in 2013, for a CAGR of 10.8%.

The global nutraceutical market is defined as aggregate sales of functional food, beverage and supplements fortified with bioactive ingredients including fiber, probiotics, protein and peptides, omega, phytochemicals and vitamins and minerals. Currently, foods, beverages and supplements equally contribute about 33% each to the total global nutraceutical market.

INTERNATIONAL SOURCES

In the global market, there are significant issues of product quality. Nutraceuticals from the international market may claim to use organic or exotic ingredients, yet the lack of regulation may compromise the safety and effectiveness of products. Companies willing to create a wide profit margin may create unregulated products overseas with low-quality or ineffective ingredients.

INDIAN NUTRACEUTICALS MARKET

Along with the growing healthcare industry in India there is an emerging trend also in Fast Moving Healthcare Goods (FMHG) in India; worldwide known as Nutraceuticals, which are by definition, ingredients with human health benefits beyond basic nutrition. Nutraceutical and functional food ingredients are ingredients with human health benefits beyond basic nutrition. According to Cygnus estimates, nutraceuticals market in 2007 was INR 18.75 billion (Hasler, 2005) Total market for Nutraceuticals in India is valued at INR 44 bn in 2009; it is estimated to reach INR 95 bn in 2013. Market comprises of two segments-Food Supplements and Vitamins and Minerals. The report provides a snapshot of the market including its segments food supplements, vitamins and minerals. An overview gives a quick picture of the market with estimated market size, growth rate and key products and examples. An analysis of drivers reveals that raising shift towards preventive therapies, increase in disposable income, increase in healthcare spending, ageing population, pharma retail growth and favourable pricing environment is driving growth in this sector.

Global nutraceuticals market is estimated at USD120 billion in 2007 growing at 7% (CAGR). The US has been the major market for nutraceuticals with India and China becoming fastest growing markets. Nutraceuticals are gaining acceptance due to their ability to address several diseases. Vitamins, Minerals and Nutrients constitute about 85% of the market while antioxidants and anti-agents account for 10% other segments such as herbal extracts occupy 5% of the market, globally. Cygnus has considered nutraceuticals along with functional foods to estimate the total market of nutraceuticals, both global and Indian market.

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