Industry Insight

Nutraceuticals

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4th & 5th Floghts, Road No. 1, Banjara Hills, Hyderabad-500034, India Tel: +91-40-23430303-05, Fax: +91-40-23430201, E-mail: info@cygnusindia.com Website: www.cygnusindia.com

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SYNOPSIS

Along with the growing healthcare industry in India there is an emerging trend in growing consumerism for 'Fast Moving Healthcare Goods (FMHG)'; worldwide known as Nutraceuticals, which are by definition, ingredients with human health benefits beyond basic nutrition. In this report, Cygnus has considered nutraceuticals along with functional foods to estimate the total market of nutraceuticals, both for global and Indian market. According to Cygnus estimates, nutraceuticals market in 2007 was INR18.75 billion and expected to grow at 20% CAGR to achieve a market size of INR27 billion in 2009. 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 globally for their ability to address several diseases. Vitamins, Minerals and Nutrients constitute about 85% of the global market while antioxidants and anti-agents account for 10% other segments such as herbal extracts occupy 5% of the market.

Large global food companies, which are always on the lookout for ways to diversify their product line and still turn a profit, have set up functional food or nutraceutical divisions. Pharmaceutical companies are now adopting the nutraceuticals and the recent trend is convergence of food manufacturing companies with pharmaceuticals to implement the collaborative research necessary for drug discovery; the move into the less expensive and time-consuming nutraceuticals research process. It is thus becoming a logical progression for many food companies to enter into nutraceuticals market.

In the view of above backdrop Cygnus has attempted to publish this report on Indian Nutraceuticals market. The report aims at recent trend in the industry, global market and its trend, estimates of the future market, growth drivers, critical success factors, issues and challenges, regulatory environment, profiles of major players and their products offering. The report has total 142 pages with eight chapters and 12 figures and 7 tables showing major industry data. The report will be useful for industry research analysts, Pharma and other food manufacturing companies, financial institutes, and research institutes interested in broad overview of the industry, market its trend and future trend.

Contents

SYNOPSIS	2
EXECUTIVE SUMMARY	10
Highlights	13
I. INTRODUCTION	15
I.I Definition of Nutraceutical	15
I.2 Classification	17
1.2.1Based on origin of ingredients	17
I.2.2 Based on nature of products	17
1.3 Product Classification	18
I.3.1 Vitamins	18
I.3.2 Antioxidants	19
I.3.3 Minerals	20
I.3.4 Herbals/Botanicals	
1.3.5 Non herbals	
I.3.6 Proteins	23
1.3.7 Fibers	
2. NUTRACEUTICALS MARKET OVERVIEW	25
2.1 Global Market Overview	25
2.1.1 Introduction	25
2.1.2 Market scenario	25
2.1.2.1Geographical segment	27
2.1.2.2 Market trends	
2.1.3 Major markets	29
2.1.3.1 US	30
2.1.3.2 Europe	30
2.1.3.3 Japan	31
2.1.3.4 Southeast Asia	31
2.1.3.5 China	
2.1.4 Outlook	33
2.2 Indian market overview	
2.2.1 Introduction	
2.2.2 Market segmentation	
2.2.2.1 Food supplements	
2.2.2 Vitamin & Mineral Supplements	
2.2.3 Market size	
2.2.4 Outlook	
3. GROWTH DRIVERS	40
3.1 Aeging population	40
3.2 Changing lifestyle	41
3.3 Increasing medical costs	
3.4 High spending power	43

3.5 Awareness of preventive medicine	44
3.6 Baby Boomers	44
3.7 Increasing malnutrition led diseases	
4. ISSUES AND CHALLENGES:	47
4.1 Intense competition	47
4.2 Functional Foods gains momentum	
4.3 Pharmaceutical and food companies join the bandwagon	
4.4 Consumer awareness	
5. CRITICAL SUCCESS FACTORS	50
5.1 Branding	50
5.2 Pricing	
5.3 Market promotion	52
5.4 Channels	
6. MAJOR PLAYERS	54
6.1 Abbott India Ltd	55
6.1.1 Company Background	55
6.1.2 Contact Address	
6.1.3 Management Team	
6.1.3.1 Board of Directors	
6.1.4. Products	57
6.1.5. Business Strategy & Competitive Advantages	57
6.1.5.1 Strategies	
6.1.5.2 Competitive Advantages	
6.1.6. Financial Details	
6.1.6.1 Revenue	
6.1.7. Outlook	
6.2 Dabur India Ltd	59
6.2.1 Company Background	
6.2.2. Contact Address	
6.2.3. Management Team	
6.2.3.1 Board of Directors	
6.2.4. Leading brands	
6.2.5. Business Strategy & Competitive Advantages	
6.2.5.1 Strategies	
6.2.5.2 Competitive Advantages	
6.2.6.1 Revenue	
6.2.7. Outlook	
6.3 Elder Pharmaceuticals Ltd	
6.3.1. Company Background	
6.3.3. Management Team	
6.3.3.1 Board of Directors	

6.3.4. Leading brands	69
6.3.5. Business Strategy & Competitive Advantages	
6.3.5.1 Strategies	
6.3.5.2 Competitive Advantages	70
6.3.6. Financial Details	
6.3.6.1 Revenue	71
6.3.7 Outlook	72
6.4 E.I.DParry (India) Limited	73
6.4.1. Company Background	73
6.4.2. Contact Address	
6.4.3. Management Team	
6.4.3.1 Board of Directors	
6.4.4. Products	
6.4.5. Business Strategy & Competitive Advantages	
6.4.5.1 Strategies	
6.4.5.2 Competitive Advantages	
6.4.6. Financial Details	
6.4.6.1 Revenue	
6.4.7. Outlook	
6.5 GlaxoSmithKline Consumer Healthcare Ltd	
6.5.1. Company Background	
6.5.2. Contact Address	
6.5.3. Management Team	
6.5.4. Products Portfolio	
6.5.5. Business Strategy & Competitive Advantages	
6.5.5.1 Strategies	
6.5.5.2 Competitive Advantages	
6.5.6. Financial Details	
6.5.6.1 Revenue	
6.5.7. Outlook	
6.6 Himalaya Herbal Healthcare	83
6.6.1. Company Background	83
6.6.2. Contact Address	
6.6.3. Management Team	84
6.6.3.1 Board of Directors	84
6.6.4. Leading brands	84
6.6.5. Business Strategy & Competitive Advantages	
6.6.5.1 Strategies	
6.6.5.2 Competitive Advantages	
6.6.6. Outlook	
6.7 Ranbaxy Laboratories Ltd	
6.7.1. Company Background	84
6.7.2. Contact Address	

6.7.3. Management Team	87
6.7.3.1 Board of Directors	
6.7.4. Leading brands	
6.7.5. Business Strategy & Competitive Advantages	
6.7.5.1 Strategies	
6.7.5.2 Competitive advantages	
6.7.6. Financial Details	
6.7.6.1 Revenue	
6.7.7. Outlook	
6.8 Zandu Pharmaceuticals	
6.81. Company Background	91
6.8.2. Contact Address	92
6.8.3. Management Team	92
6.8.3.1 Board of Directors	92
6.8.4. Leading brands	92
6.8.5. Business Strategy & Competitive Advantages	93
6.8.5.1 Strategies	93
6.8.6. Financial Details	93
6.8.6.1 Revenue	93
6.8.7. Outlook	94
6.9 Zydus Cadila Health Care	95
6.9.1. Company Background	95
6.9.2. Contact Address	
6.9.3. Management Team	96
6.9.3.1 Board of Directors	96
6.9.4. Leading brands	97
6.9.5. Business Strategy & Competitive Advantages	97
6.9.5.1 Strategies	97
6.9.5.2 Competitive Advantages	98
6.9.6. Financial Details	
6.9.6.1 Revenue	98
6.9.7. Outlook	99
6.10 Amway India	
6.10.1. Company Background	
6.10.2. Contact Address	
6.10.3. Management Team	
6.10.4. Leading brands	
6.10.5. Business Strategy	102
6.10.5.1 Strategies	
6.10.6. Outlook	
6.1 Tablets India Limited	102
6.11.1. Company Background	
6.11.2. Contact Address	
6.11.3. Management Team	104

6.11.3.1 Board of Directors	104
6.11.4. Leading brands	104
6.11.5. Business Strategy & Competitive Advantages	
6.11.5.1 Strategy	
6.11.5.2 Competitive advantage	
6.11.6. Outlook	
6.12 Raptakos, Brett & Co.Ltd	105
6.12.1. Company Background	
6.12.2. Contact Address	
6.12.3. Products	
6.12.4. Outlook	
6.13 Sami Labs	109
6.13.1. Company Background	109
6.13.2. Contact Address	
6.13.3. Management Team	110
6.13.4. Leading Products	
6.13.5. Business Strategy & Competitive Advantages	
6.13.5.1 Strategies	
6.13.5.2 Competitive Advantages	
6.13.6. Outlook	
6.14 British Biologicals	
6.14.1. Company Background	
6.14.2. Contact Address	
6.14.3. Management Team	
6.14.3.1 Board of Directors	
6.14.4. Leading brands	
6.14.5 Business Strategy & Competitive advantages	
6.14.5.1 Strategy	
6.14.6. Outlook	
REGULATIONS	
7.1 USA	
7.2 European Union	
7.3 Japan7.4 India	
8. FUTURE OUTLOOK	
ANNEXURE I	126
Dietary Supplement Health and Education Act of 1994	126
ANNEXURE II	
BIBLIOGRAPHY	142
ANNEXURE III	144

Industry Insight-Nutraceuticals

GLOSSORY	144
ANNEXURE IV	146
ABBREVIATION	146

List of Tables

- Table: 1.1 Nutraceuticals classification
- Table: 1.2 Common vitamins nutrients and their associated health benefits
- Table: 1.3 list of some Antioxidants found in Food
- Table: 1.4 Common mineral nutrients and their associated health benefits
- Table: 1.5 Herbals/Botanicals
- Table: 2.1 Major Global players
- Table: 2.2 Indian Food supplements Segmentation

List of Charts

- Fig: 2.2 Nutraceuticals Market in Southeast Asia
- Fig: 2.3 Nutraceutical Market Outlook
- Fig: 2.4 Indian nutraceutical market segments
- Fig: 2.5 Indian food supplements segmentation
- Fig: 2.6 Indian vitamins and supplements segments
- Fig: 2.7 Indian Nutraceutical Market Size
- Figure 3.1: Indian Population according to their Age Group
- Figure: 3.2 Growth in diseases related to life style (FY2006)
- Figure: 3.4 Indian per Capita Income (FY2004-FY2007)
- Fig: 8.1 Nutraceuticals ingredients demand forecast
- Fig: 8.2 Global Nutraceutical Market Outlook
- Fig: 8.3 Indian Nutraceutical Market Outlook

EXECUTIVE SUMMARY

Global nutraceuticals market in 2007 is estimated to be USD120 billion and has been growing at a CAGR of 6.8%. However, functional foods market is growing faster at a CAGR of 12%. The US has been the major market with 36% of market share in the global market followed by Asia at 30% and Europe at 24%. In Asia, Japan is the largest market at 70% market share. India, China, Taiwan and Korea are among the fast growing markets.

Indian nutraceutical market is estimated at INR18.75 billion in 2007 and is expected to grow at CAGR of about 21% to reach INR27 billion in 2009. Nutraceutical market comprises food supplements (also called functional foods) vitamins and minerals supplements. Currently food supplements constitute about 60% of the market, vitamins/minerals supplements contributing the balance.

Worldwide, the demand for nutraceuticals is driven by growing consumer awareness of diet-disease links, ageing populations, rising healthcare costs, and advances in food technology and nutrition. Currently, preventive healthcare concerns like cholesterol control, weight control, and avoidance of osteoporosis are the major targets for nutraceuticals, followed by women care during pregnancy, blood pressure control, diabetes, GI disorders, menopause-related ailments and lactose intolerance. Gender and age segmentation increases the dietary supplements markets as the products are aimed at such target customers. As nutraceuticals are not subject to stringent regulations for new product approvals innovative companies can take the products to market faster. Globally a number of nutraceutical products are sold through internet beside traditional channels.

Nutraceuticals ingredients with large demand include soy protein nutrients, the functional food ingredients lutein, lycopene, omega-3 fatty acids, probiotics and sterol esters, the essential minerals calcium and magnesium, the herbal extracts garlic and green tea; and the non-herbal extracts chondroitin, glucosamine and coenzyme Q10.

Last few years saw a paradyme shift in the lifestyle of an average Indian, which has led to the new generation of health food products christened as functional food products. Functional food also termed as the 'nutraceutical' products (a hybrid of nutrition and pharmaceutical) is any fresh or processed food claimed to have health-promoting ingredients apart from its basic nutritional function.

Food supplements includes food products and supplements, malted beverages, protein powder, pediatric nutrition, fruit-based products (under beverages category), sports products (energy boosters), and clinical products, and is valued at INR11.25 billion in 2007. Vitamins and minerals, which includes Vitamin-B complex, multivitamins, anti-oxidants, protein supplements, enteral nutrition, Vitamin-B12 and metabolites and Vitamin-C with Minerals, is valued at INR7.5 billion.

Demographic factors like age group, per capita income, lifestyle, food habits and increase in lifestyle diseases are the major growth factors on which the growth of health supplements depends. Ageing population and focus on preventive care will create new opportunities and drive healthy growth of pharmaceutical and nutraceutical companies. Urban population in India is growing at a drastic pace, which is leading to increase in lifestyle diseases, thus creating a demand for nutraceuticals. Consumers are increasingly becoming health conscious and are realising the need for dietary supplements to help them cope up with the fast-changing pace of life, which has put them at the risk of diabetes, cholesterol, heart ailments, arthritis and so on. Advertisement through electronic media has played a great role in creating awareness among the urban consumers about health nutrients and supplements.

Players in the market include Pharma companies as well as Food and beverage companies. Critical success factors for the industry include branding, pricing, market promotion and distribution channel, which allow marketers to align their products with health-oriented causes, consumers and medical practitioners so as to create awareness among the consumers. In Indian context, success will depend more on right positioning and pricing with intense promotional activities. Marketing strategies of companies differ depending on product portfolio and target markets. For health products like breakfast cereals, fruit juices and health drinks the target population is mainly the metro and urban populace. However, with increasing number of players the food market is getting more

competitive and in the last three years, a good number of large food processors have entered Indian food market. Growth of organized retailing has definitely proved to be a market booster with a lot of medium food innovators also venturing into healthy food marketing.

In the nutraceutical industry, building strong brand equity generates greater income, while increasing the cash flow. This in turn increases the market share and creates a high-value brand. Launching a nutraceutical brand with a solid marketing campaign can often help overcome potential pitfalls that may occur down the road and consumer market research helps in determining the direction a company needs to take to move a product forward. Most nutraceuticals are highly priced and hence the tag of exotic commodity remains in spite of awareness. Pricing has so far been one of the critical factors responsible for slower growth rate of nutraceutical products. Although nutraceuticals industry claims to reach the length and breadth of the population, the target consumers still remain only the urban elite in India.

India is well developed in areas like fermentation processes, plant extraction and chemical synthesis. This coupled with low labour cost, can offer cost effective nutraceuticals products from India. The market leader of Chyawanprash, Dabur rolled out its new initiative, Project 'DARE' (Driving Achievement of Retail Excellence), aiming to reorganise the distribution structure and influence the consumer at the point of purchase. Major players in this industry include, direct selling companies like Amway, MNCs like GSK, Ayurvedic companies such as Zandu, Dabur India, Himalaya Drugs and domestic pharma companies like Ranbaxy, Elder Pharmaceuticals, Cadila Healthcare.

As per Cygnus estimates, the global demand for nutraceuticals is likely to reach USD156 billion by 2011, growing at a CAGR of 6.8%. The nutraceuticals ingredients demand is likely to grow from USD12.4 billion in 2006 to USD16.6 billion in 2011, growing at a CAGR of 6.1%. This presents an excellent opportunity for exports of ingredients as well as nutraceuticals products.

Highlights

- Nutraceutical and functional food ingredients are by definition, ingredients with human health benefits beyond basic nutrition.
- Global nutraceuticals market in 2007 is estimated at USD 120 billion and it is growing at a CAGR of 6.8%.
- The US is the major market with 36% of market share followed by Europe 24% and Asia (including Japan) at 30% in the global market.
- Germany, France the UK, Italy and Switzerland currently drive the European market for nutraceutical products.
- Japan is the second largest market by country in the world for nutraceutical products after the US and its functional food industry is estimated to be USD26.4billion.
- The nutraceuticals market in Southeast Asia shares 6% of the global market in 2007 to USD7.2 billion and is likely to grow to 8% in 2009 to USD10.96 billion.
- The Asian market is likely to grow at a higher rate occupying 35% share in the global market in 2009
- Globally major companies in the nutraceuticals market are dominated by the US companies followed by Germany, France and Japan.
- The top five nutraceutical ingredient global competitors are Solae, Cargill, DSM Nutritional Products, ADM Natural Health and Nutrition, and BASF.
- In 2007, Indian nutraceutical market was estimated at INR18.75 billion and is growing at the CAGR rate of 21.23% and is estimated to reach INR27 in 2009.
- The Indian nutraceutical market comprises of food supplements valued at INR11.25 and vitamins & mineral supplements at INR7.5 billion in 2007.
- Food supplements include food products and supplements, malted beverages, protein powder, paediatric nutrition, fruit-based products, sports products, and clinical products.

- Vitamins and minerals include Vitamin-B complex, multivitamins, anti-oxidants, protein supplements, enteral nutrition, Vitamin-B12 and metabolites and Vitamin-C with minerals.
- The growth in nutraceuticals market is expected to be driven by the functional foods market, with high growth predicted in the vitamins, minerals and supplements (VMS) sector in the coming years.
- Demographic factors like age group, per capita income, lifestyle, food habits and increase in diseases are the major growth factors on which the growth of health supplements depends.
- The critical successes factors include branding, pricing, market promotion and distribution channel which allow marketers to align their products catering the consumer needs.
- Worldwide, the demand for nutraceuticals is driven by growing consumer awareness of diet-disease links, ageing populations, rising healthcare costs, and advances in food technology and nutrition.
- High growth opportunities are likely to be seen in the coming years in soy protein nutrients, the functional food ingredients like lutein, lycopene, omega-3 fatty acids, probiotics and sterol esters, the essential minerals calcium and magnesium, the herbal extracts garlic and green tea and the non-herbal extracts chondroitin, glucosamine and coenzyme Q10.
- Global demand for nutraceuticals is likely to reach USD156billion by 2011 growing at a CAGR of 6.8%
- Indian nutraceutical market is expected to be driven by food products and supplements segment.
- The nutraceutical industry in India presents an interesting investment opportunity, characterized by low regulatory barriers and rapidly rising consumer demand in the domestic market.

I.INTRODUCTION

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 merged pharmaceutical/ agribusiness/ nutrition conglomerates. In recent years there is a growing interest in nutraceuticals which provide health benefits and are providing preventive options for the ageing population worldwide for keeping them away from various lifestyle diseases. Nutrients, herbals and dietary supplements are major constituents of nutraceuticals which make them instrumental in maintaining health, act against various disease conditions and thus promote the quality of life. Food products fortified with natural nutrients and other supplements has taken a big way in the OTC market along with some vitamins and minerals supplements. While all good for Pharma and food manufacturing companies to see the sudden spurt in various nutraceuticals all the more it is equally important to understand the market perception, its dynamics and critical success factors. Cygnus Research has attempted to define the market space, market size and growing segments in the market, both global and domestic along with some major players.

I.I Definition of Nutraceutical

A variety of terms have appeared world-wide such as nutraceuticals, medifoods, vitafoods, functional foods and the more traditional dietary supplements and fortified foods. However, the term Functional foods have become the predominant one even though several organizations have attempted to differentiate this emerging food category.

The term "Functional Foods" was first introduced in Japan in the mid-1980s and refers to processed foods containing ingredients that aid specific body functions, in addition to being nutritious. Presently, there is no universally accepted term for functional foods.

Health Canada defines a functional food as similar in appearance to a conventional food, consumed as part of the usual diet, with demonstrated physiological benefits, and/or to reduce the risk of chronic disease beyond basic nutritional functions" and a nutraceutical

as a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with foods.

In Korea, functional foods are defined as dietary supplement whose purpose is to supplement the normal diet and have to be marketed in measured doses, such as in pill, tablets.

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 DeFelice, 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 disease.

Functional foods, as defined by the Institute of Medicine in Washington, are those foods that encompass potentially healthful products including any modified food or ingredient that may provide a health benefit beyond the traditional nutrients it contains. Functional foods can include foods like cereals, breads and beverages which are fortified with vitamins, herbs or nutraceuticals.

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 and subsequently increased the use of nutraceuticals.

1.2 Classification

1.2.1 Based on origin of ingredients

Nutraceuticals can be classified based on the origin of the beneficial ingredient and/or the therapeutic benefits claimed.

Table: 1.1 Nutraceuticals classification		
Ingredient	Therapeutic use	
Antioxidants, carotenoids	Bone & joint health	
Dairy-based ingredients	Cancer risk reduction	
Fibres and carbohydrates	Cardiovascular health	
Minerals	Cognitive and mental function	
Nutritional lipids and oils	Diabetes	
Phytochemicals, plant extracts	Energy & endurance	
Probiotics and prebiotics	Eye health	
Proteins, peptides, amino acids	Gut health	
Soy-based ingredients	Immune system	
Vitamins & premixes	Maternal & infant health	
	Respiratory health	
	Skin health	
	Weight management	
	Women's health	
Source: Cygnus Research		

1.2.2 Based on nature of products

- Nutraceuticals based on the nature of the products can be grouped into the following three broad categories:
 - Substances with established nutritional functions, such as vitamins, minerals, amino acids and fatty acids - Nutrients or known as VMS (Vitamins, Minerals and Supplements)
 - 2. Herbs or botanical products as concentrates and extracts Herbals

3. Reagents derived from other sources (e.g. pyruvate, chondroitin sulphate, steroid hormone precursors) serving specific functions, such as sports nutrition (energy boosters), weight-loss supplements and meal replacements – Dietary supplements.

1.3 Product Classification

• Based upon the products

While Nutraceuticals are defined as non-specific biological therapies used to promote wellness, prevent malignant processes and control symptoms they can be broadly categorized as given below.

- 1. Vitamins
- 2. Antioxidants
- 3. Minerals
- 4. Herbals/Botanicals
- 5. Non-Herbals
- 6. Proteins
- 7. Fibers

1.3.1 Vitamins

In humans, there are thirteen vitamins, divided into two groups, the four fat-soluble vitamins (A, D, E and K) and the nine water-soluble vitamins (eight B vitamins and vitamin C).

Table: 1.2 Common vitamins nutrients and their associated health benefits	
Nutrients	Health benefits
	Fat Soluble Vitamins
Vitamin A	Antioxidant, essential, for growth and development, maintains healthy vision, skin and mucous membranes, may aid in the prevention and treatment of certain cancers and in the treatment of certain skin disorders.
Vitamin D	Essential for formation of bones and teeth, helps the body absorb and use calcium
Vitamin E	Antioxidant, helps form blood cells, muscles, lung and nerve tissue, boosts the immune system
Vitamin K	Essential for blood clotting

Water Soluble Vitamins		
Vitamin C	Antioxidant, necessary for healthy bones, gums, teeth and skin, helps in wound healing, may prevent common cold and attenuate its symptoms	
Vitamin B1	Helps to convert food in to energy, essential in neurologic functions	
Vitamin B2	Helps in energy production and other chemical processes in the body, helps maintain healthy eyes, skin and nerve function	
Vitamin B3	Helps to convert food in to energy and maintain proper brain function	
Vitamin B6	Helps to produce essential proteins and convert protein in to energy	
Vitamin B12	Helps to produce the genetic material of cells, helps with formation of red blood cells, maintenance of central nervous system and synthesize amino acids and is involved in metabolism of fats, protein and carbohydrates	
Folic acid	Necessary to produce the genetic materials of cells, essential in first three months of pregnancy for preventing birth defects, helps in red blood cell formation, protects against heart disease	
Pantothenic acid	Aids in synthesis of cholesterol, steroids and fatty acids, crucial for intraneuronal synthesis of acetylcholine	
	Vitamin like compounds	
Biotin	Required for various metabolic functions	
L- Carnitine	Oxidation of fatty acids, promotion of certain organic acid excretion and enhancement of the rate of oxidative phosphorylation	
Choline	Lipotropic agent used to treat fatty liver and disturbed fat metabolism	
Vitamin F	Involved in proper development of various membranes and synthesis of prostaglandins, leukotrienes and various hydroxy fatty acids	
Inositol	Lipotropic agent necessary for amino acid transport and movement of potassium and sodium	
Taurine	Aids in retinal photoreceptor activity, bile acid conjugation, white blood cell antioxidant activity, CNS neuromodulation, platelet aggregation, cardiac contractility, sperm motility, growth and insulin activity	
Source: Indian Journal of Pharmacology, Cygnus Research		

1.3.2 Antioxidants

Antioxidants are substances that may protect our body cells against the effects of free radicals. Free radicals are molecules produced when our body breaks down food, or by environmental exposures like tobacco smoke and radiation. Free radicals can damage cells, and may play a role in heart disease, cancer and other diseases.

Table:1.3 A list of some Antioxidants found in Food		
Bilberries	These are rich in flavonoids - antioxidant nutrients which may help to protect	
Carnosine	the body's cells from damage by excess free radicals It is a multi-potent super-antioxidant which stabilizes and protects the cell membrane. It is not only effective in prevention, but it is also active after free radicals react to form other dangerous compounds, like lipid peroxides and	
	secondary products in turn protects the tissues from damaging 'second-wave' chemicals.	
Carotenoids	These are perhaps best known for their ability to be converted to vitamin A, which is essential for healthy vision and reproduction, and for maintaining body tissues. Carotenoids are also powerful antioxidants on their own right.	
Co-Enzyme Q10	It is involved in the body's metabolic processes, particularly in the release of energy from food. It is also a potent antioxidant.	
Green Tea	This is an excellent source of potent polyphenols, a strong antioxidant and inhibitor of harmful Angiogenesis	
Selenium	It is recognized to be a trace mineral which prevents rancidification (lipid peroxidation) of the cells and cell damage and which delays the pathological ageing process It also counteracts cancer and chromosome damage as well as counteracts adverse effects of heavy metals and other toxic substances in the	
Soy&Isoflavones	body Isoflavones are Natural Phytoestrogens found in abundance in soya beans these offer no. of benefits to related to:	
	menopause symptom relief	
	• osteoporosis	
	cardiovascular diseaseimmunity	
	• cancer	
Zinc	It is vital to about 200 different enzymes, to the formation of bone tissue, in the healing of wounds and sores, to the production of proteins, the regulation of ribosomal, ribonucleic acid synthesis and insulin and in the carbohydrate metabolism.	
Source: Indian Journal of Pharmacology, Cygnus Research		

1.3.3 Minerals

Minerals are natural inorganic compounds. Humans need small amounts of about 14 minerals to maintain normal body function and good health. There are two types of minerals: Macro minerals and Trace minerals.

Table 1.4 Common mineral nutrients and their associated health benefits		
Minerals		
Calcium	Essential for building bones and teeth and maintaining bone strength, important in nerve, muscle and glandular functions	
Iron	Helps in energy production, helps to carry and transfer oxygen to tissues	
Magnesium	Essential for healthy nerve and muscle function and bone formation, may help prevent premenstrual syndrome (PMS)	
Phosphorous	Essential for building strong bones and teeth, helps in formation of genetic material, energy production and storage	
Trace elements		
Chromium Cobalt	With insulin helps to convert carbohydrates and fats into energy Essential component of vitamin B12, but ingested cobalt is metabolized in vivo to	
Coount	form the B12 coenzymes	
Copper	Essential for hemoglobin and collagen production, healthy functioning of the heart, energy production, absorption of iron from digestive tract	
Iodine	Essential for proper functioning of the thyroid	
Selenium	Antioxidant, essential for healthy functioning of the heart muscle	
Zinc	Essential for cell reproduction, normal growth and development in children, wound	
	healing, production of sperm and testosterone	
Source: Indian Jour	nal of Pharmacology, Cygnus Research	

1.3.4 Herbals/Botanicals

Herbals are as old as human civilization and they have provided a complete storehouse of remedies to cure acute and chronic diseases. The knowledge of herbals has accumulated over thousands of years so that today we possess many effective means of ensuring health care. Numerous nutraceuticals are present in medicinal herbs as key components. A list of commonly known herbal and phytochemical is given below.

Table: 1.5 Herbals/Botanicals	
Compound	Therapeutic activity
Aloe vera gel	Dilates capillaries, anti-inflammatory, emollient, wound healing properties
(Aloe vera L. N.L. Burm.)	
Chamomile	Antiinflammatory, spasmolytic, antimicrobial, wound healing
(Matricaria recutita L.)	
Echinacea (<i>Echinacea purpurea L.</i>) Eleuthera	Immunostimulant, treatment of cold and flu symptoms Adaptogen
(Eleutherococcus senticosus Rupr. & Maxim.,	
Maxim)	
Ephedra	Bronchodilator, vasoconstrictor, reduces bronchial edema, appetite suppressant
(Ephedra sinica Stapf., Ephedra intermedia Schrank., Ephedra equisetina Bunge.)	

Industry Insight-Nutraceuticals

Evening primrose oil Dietary supplement of linoleic acid, treatment of

atopic eczema

(*Oenothera biennis L.*)

Feverfew Treatment of headache, fever and menstrual problems,

prophylactic to reduce frequency, severity and duration

(Tanacetum parthenium L.) of migraine headaches

Garlic Antibacterial, antifungal, antithrombotic, hypotensive,

fibrinolytic, antihyperlipidemic, antiinflammatory

(Allium sativum L.)

Ginger Carminative, antiemetic, cholagogue, positive

inotropic, treatment of dizziness

(Zingiber officinale Rosc.)

Slippery elm Mucilaginous demulcent, emollient and nutrient, used

to sooth irritated mucous membranes, ulcerations of

the digestive tract

Source: Indian Journal of Pharmacology, Cygnus Research

1.3.5 Non herbals

(Ulmus rubra Muhl.)

Non herbal category includes chondroitin, glucosamine and coenzyme Q10 as well as dietary supplements which have been developed to manage a variety of diseases. The prepackaged nutritionally balanced meals influence multiple risk factors for patients with cardiovascular disease. Ketogenic diets, comprised of foods high in fat and low in protein and carbohydrate content, have been reported to improve seizure control. Cereals and grains is an area of nutraceuticals in which calcium fortification is very strong. Kellogg's is a leader with calcium fortified all-bran plus and nutrigrain bars. Burgeon is bread containing soya flour and linseeds, which provide phytoestrogens, natural substances that mimic the structure of hormone oestrogen which may prevent against both hot flushes and breast cancer. Other common foods that may have potential therapeutic value include edible mushrooms like, Lentinus (shiitake), Pleurotus (oyster), Auricularia (mu-er), Flammulina (enokitake), Tremella (yin-er), Hericium, and Grifola (maitake) have varying degrees of immunomodulatory, lipid lowering, antitumor and other beneficial health effects.

Zbar and NiteBite are two products in the form of bars that contain sucrose, protein and uncooked starch in order to provide continuous glucose release to diabetics during the night. The two nutraceuticals namely glucosamine sulfate and chondroitin sulfate are effective and safer to alleviate symptoms of osteoarthritis. An emerging area of nutraceuticals is that of dairy foods containing friendly or probiotic bacteria claimed to

promote gut health. Bio yoghurts containing *Lactobacillus acidophilus* and Bifidobacteria lead the Sector. Drinks are a fast developing area of functional foods. A new range of herb and vitamin enhanced drinks called Phuse claims to help overcome problems ranging from postmenstrual syndrome to lack of energy.

1.3.6 Proteins

Proteins are complex organic compounds. The basic structure of protein is a chain of amino acids. Protein-containing foods are grouped as either complete or incomplete proteins.

- 1. Complete proteins contain all nine essential amino acids. Complete proteins are found in animal foods such as meat, fish, poultry, eggs, milk, and milk products such as yogurt and cheese. Soybeans are the only plant protein considered to be a complete protein.
- 2. Incomplete proteins lack one or more of the essential amino acids. Sources of incomplete protein include beans, peas, nuts, seeds, and grain. A small amount of incomplete protein is also found in vegetables.
- 3. Plant proteins can be combined to provide all of the essential amino acids and form a complete protein. Examples of combined, complete plant proteins are rice and beans, milk and wheat cereal, and corn and beans.

1.3.7 Fibers

Fiberous molecules include the complex carbohydrates cellulose, hemicelluloses, pectin, algal polysaccharides and mucilages along with the polyphenolic structural molecule lignin. The health promoting benefits of higher fiber diet has made this class of nutrients very recognizable in the rapidly developing nutraceutical field. Fiber consumption has been linked in decreased incidence of heart disease, various types of cancer, and diverticulosis. On the basis of their water-solubility, dietary fibers are classified into two major categories and a balanced intake of both types is recommended for optimum digestive health. Insoluble fibers consist of lignin, cellulose, hemicellulose, and bran as well as digestion-resistant starches, and soluble fibers include polyfructoses [inulin, fructooligosaccharides (FOS)], galactooligosacchardies, gums, mucilages, and pectins.

A variety of fiber supplements are currently available as reconstitutable powders, drink mixes, capsules, as well as swallowable or chewable tablets to correct dietary fiber deficiencies. Fiber supplements based on psyllium or methylcellulose generally swell in water, becoming sticky or gummy, imparting high viscosity and a gritty mouth feel. Such fibers must be consumed with large quantities of fluids and have a low consumer acceptance. One of the most common nutraceuticals is whole grains because of their fiber benefits, but out bran is not as widely incorporated into bakery foods as other whole grains. Out brans are an ideal nutraceutical because they provide beta-glucans. Beta-glucans are carbohydrates produced by glucose molecules. Found naturally in some grains, beta-glucans are a soluble dietary fiber and the only glucan found to be effective in preventing coronary heart disease by significantly lowering LDL (bad) cholesterol and increasing HDL (good) cholesterol. Sources of fiber are whole grains, including whole wheat, oats, brown rice, acorn squash, beans, broccoli, Brussels sprouts, cabbage, green peas, kale, radishes, spinach, winter squash, and yams. There are soluble and insoluble fibers from apples, blackberries, blueberries, pears, raspberries, and strawberries.

2. NUTRACEUTICALS MARKET OVERVIEW

2.1 Global Market Overview

2.1.1 Introduction

Nutraceutical and functional food ingredients are by definition, ingredients with human health benefits beyond basic nutrition as they are sold as isolated, purified components in pharmacological doses for specific ailments. Health is of vital importance to consumers of all ages, demographic groups and countries, so one would expect a strong demand for nutraceutical foods and beverages which provide specific health benefits. The international market for nutraceuticals is rapidly expanding and new research is constantly being conducted. New products are appearing on the market, some with novel therapeutic applications.

2.1.2 Market scenario

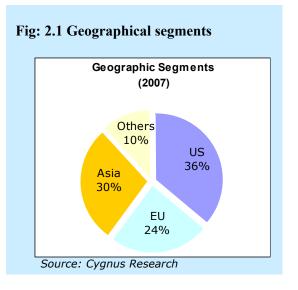
In the global marketplace nutraceuticals and functional foods have become a multi-billion dollar industry. Currently global nutraceuticals market as per Cygnus estimates in 2007 was USD 120 billion and it is growing at a CAGR of 6.8%. The US has been the major market with 36% of market share in the global market followed by Europe 24% and Asia at 30% of the global market share. In Asia, Japan is the largest market at 70%market share. India and China and Southeast countries such as Taiwan and Korea are becoming fastest growing markets. Japan is the second largest market by country and its per capita consumption of nutraceuticals is higher (USD166 per annum) than the US (USD136 per annum) and the Europe (USD92 per annum). The popularity of products marketed as functional foods and nutraceuticals is highly variable and often dependent upon local allegiances, the industry as a whole has an international presence and operates in many countries and has potential to grow in a major way.

The industry operates with a network of supportive stake holders thus providing consumers with health products having a beneficial physiological effect on the body besides providing nutrients. The stakeholders can be grouped under two core groups:

primary and secondary. The primary stakeholders include the producers (farmers/growers) of the plant products, food processing and pharmaceutical companies who manufacture products and byproducts, the consumers who directly or indirectly buy them for the purpose of willful consumption, the government and regulatory agencies who have the responsibility to assure proper development of the industry. University and research institutes for developing innovative ideas and techniques and physicians are included in the primary group which is responsible for survival and wellbeing of the industry. The secondary group consists of stakeholders that help in further expansion of the industry includes dieticians, alternative health practitioners, naturopathists, and herbalists who advocate for nutraceutical and functional food products making them acceptable to the common public, insurance companies providing security to the manufacturing companies, retailers helping in the sale and distribution of the manufactured products and environmentalists who promote the industry by supporting use of these products. The two core groups of stakeholders rotate around the central industrial pivot of this emerging industry. 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 niche or specialized markets. Development of new products with distinctive genetics, ecotype could provide local producers with access to more stable and specialized markets. Worldwide, the demand for nutraceuticals is driven by growing consumer awareness of diet-disease links, aging populations, rising health care costs, and advances in food technology and nutrition. Currently, health concerns like cholesterol reduction, cardiovascular disease and osteoporosis are the most attractive targets for nutraceuticals, followed by child development, high blood pressure, diabetes, GI disorders, menopause-related ailments and lactose intolerance.

2.1.2.1 Geographical segment

The global market is dominated by the US having a market share of 36% followed by European market having 24%share and Asia with 30% whereas rest of world has 10% of market share in 2007 as per the Cygnus estimates. In Europe Germany, France, UK, Italy and Switzerland dominate the market with 20%, 25%, and 8% 11% and11% shares respectively. In the Asian continent Japan sweeps the market share by 22% of the global market



where as remaining 8% share is shared among the other Asian countries. Vitamins, Minerals and Nutrients constitute about 85% of the market while antioxidants and antiagents account for 10% other segments such as herbal extracts occupy 5% of the market, globally. Soft drinks and dairy products segment due to their wide acceptance as a part of healthy diet are likely to grow faster than other segments.

2.1.2.2 Market trends

The nutraceutical industry has the potential to support environmental initiatives, reduce health care costs, foster economic development in rural communities, and help manufacturers to diversify. Consumers everywhere in the world want to improve health especially in developed countries like US, European countries like UK, Germany France and Japan by improving one's diet. In the present scenario consumers are following crash and fad diets and popping vitamin pills to make up the deficiency in their diet. Increasing health consciousness has been one of the most important stimulating factors for rapid global growth of the nutraceutical and functional food industry in the world. Gender, Age Segmentation Increases the dietary supplements markets as the products are aimed at target customers. Products aimed at women have been increasing steadily from past with a strong basis that older females due to menopause problems needs additional nutritional supplements in their regular diet. Introductions of dietary supplements for pregnant

women and new mothers are also on the rise globally catering to the specific target consumers. The children's segment remains important for manufacturers trying to develop a younger consumer base in the world over. In the present scenario parents are increasingly encouraged to rely on a healthy balanced diet to provide their children with vitamins and minerals, rather than substituting their child's diet with tablets, drops or chews. The children's market with interesting new products such as omega-3 essential fatty acids (EFAs) has seen a notable growth in the segment. Vitamins, supplements, and other nutraceuticals comprise one of the fastest growing industries on the Internet with online buying having less stringent regulations. Consumers are purchasing a wide range of nutraceuticals, spending several billion dollars on vitamins supplements, and functional foods.

In terms of the industry, trends that are emerging as more and more pharmaceutical companies, a sworn enemy of dietary supplements for years, are now adopting the nutraceuticals. Large food companies, are constantly on the lookout for ways to diversify their product line have set up functional food or nutraceutical divisions. The Pharmaceutical companies have already set up to implement the extensive research necessary for drug discovery; the move into the less expensive and time-consuming nutraceuticals research process is a logical progression. Convincing consumers that products with medical health claims are really good for them is a hard task. nutraceutical ingredients market is presently characterized by many small players with only few market leaders. The US market is the largest consumer mainly due to broad and increasing range of nutraceuticals products produced in the country. At the international level there are several ongoing projects in the nutraceuticals sector in the area of cholesterol, cardiovascular, osteoporosis, preventing diseases like pediatrics, hypertension, diabetics, and menopause and lactose intolerance.

The demand for the raw materials in the European market is slightly less as compared to the US. Due to strong economic growth in China and India and diversification of food, beverage and drug production capabilities the demand is likely to rise. The global market demand for nutraceuticals ingredients lies in soy protein nutrients, the functional food ingredients lutein, lycopene, omega-3 fatty acids, probiotics and sterol esters, the essential minerals calcium and magnesium, the herbal extracts garlic and green tea; and the non-herbal extracts chondroitin, glucosamine and coenzyme Q10. The top five nutraceutical ingredient global competitors are Solae, Cargill, DSM Nutritional Products, ADM Natural Health and Nutrition, and BASF. Globally major companies in the nutraceuticals market are dominated by the US companies followed by Germany and France. The list is given below in the table.

Table:2.1 Major Global players				
Companies	Country			
Advanced Nutraceuticals, Inc.	US			
Archer Daniels Midland Company	US			
BASF AG	Germany			
Beaufour-Ipsen	France			
Bayer AG	Germany			
Ceapro, Inc.	Germany			
GlaxoSmithKline plc	UK			
Laboratories Arkopharma SA	France			
Leiner Health Products	US			
Mead Johnson Nutritionals	US			
NBTY, Inc.	US			
Rexall Sundown, Inc.	US			
Novartis AG	Switzerland			
Nutraceutical International Corp.	US			
Ocean Nutrition Canada	Canada			
Perrigo Company	US			
U.S. Nutraceuticals LLC	US			
Wyeth	US			
Source: Cygnus Research				

2.1.3 Major markets

The universal desire to be healthier is driving the nutraceuticals market. Introduced in the 1990s, nutraceuticals were successful in the United States and Europe. The major market covered are USA being the largest market occupying about one third of the global market

with second largest market by country Japan, Europe and emerging markets in Southeast Asia region comprising of six major countries like Thailand, the biggest market in terms of revenue with USD1.27billion in 2007 as per the Cygnus estimates followed by Taiwan (1.26billion), Malaysia (471m), Singapore (135m), and Philippines (142.2m).

2.1.3.1 US

The US currently possesses the largest and most rapidly expanding functional food and nutraceutical market in the world. The US is the leading market, accounting for more than one-third of the global market. The estimated value for nutraceuticals in 2007 is USD 42billion. About half of the food market of US is related to use of nutraceuticals and functional food products. The Canadian nutraceutical and functional food market is relatively young and is growing as compared to the US where as in Central, Latin and South America, nutraceutical markets are still developing. The fastest growing nutraceutical market in the US is weight-loss products, according to the Nutrition Business Journal. With more than 120 million overweight Americans and 17 million diabetics, demand is growing for foods or supplements that increase metabolism, suppress or satiate appetite, and control blood sugar. Sales of functional products are rising across all food and drink categories in the US but growth is hampered by consumers' mistrust of manufacturers' claims of the nutraceutical products as convincing them with medical health claims which is really beneficial for them is a hard.

2.1.3.2 Europe

A general trend toward health-consciousness, combined with demographic factors such as stabilizing levels of income and an ageing population, have resulted in an increasingly health conscious consumer base in Europe. Moreover, with the increased use of preventative medicines and self-treatments and constraints on health-care funding, Europe has become a significant market for nutraceutical products. The nutraceuticals and functional foods industry growth has been slow as compared to US and Japan mainly

due to restricted growth within the industry through out the Europe, encompassing strict regulations governing food labeling, product formulation, food processing, packaging, marketing, registration and licensing details. Germany, France the UK, Italy and Switzerland currently drive the European market for nutraceutical products, which make up 24% of the global market. The market share of Germany as per the Cygnus estimates in 2007 was USD5.76billion, where as that of France was USD7.2 billion and that of UK was USD2.3 billion.

2.1.3.3 Japan

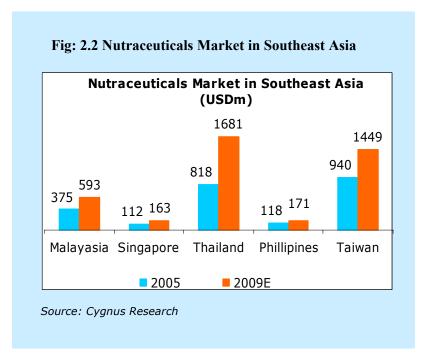
Japan is the second largest market by country in the world for nutraceutical products after the United States. Its functional food industry was estimated to have a value of USD26.4billion. Two types of functional foods have been approved by the Japanese government those with approved health claims or FOSHU (Foods for Specified Health Use) and foods that may provide health benefits (without any health claims). The country being called as country of seniors has 24.3 million (senior) people in the total population of 127 million. The ratio stands as one in every five are 65 years or older. The life expectancy for Japanese women (85.2) and men (78.3) is the longest in the world. The largest population group, baby boomers, in Japan is already reaching age 50 and the trend will continue for the next 8-10 years as older people tend to consume more nutraceuticals there by increasing the demand in Japan in the coming years.

2.1.3.4 Southeast Asia

Other large, emerging International markets for nutraceuticals in South-East Asia are seen in Taiwan, Thailand, Philippines, Vietnam, Malaysia, North and South Korea and Singapore. An increasingly hectic pace of life is now becoming commonplace in Asian countries. The nutraceuticals market in Southeast Asia has high growth potential and market share of 6% of the global market in 2007 to USD7.2 billion and is likely to grow to 8% of the global market share in 2009 to USD10.96 billion. The strategies of the nutraceutical manufacturing companies must be to invest heavily in advertising to help

consumers understand the health benefits. The region with its large population shows significant potential for manufacturers and the focus is on weight management which is driving the growth of the nutraceuticals market for weight-loss products especially in Thailand, Vietnam and Singapore. The Thailand market is one of the highest revenue

earners mainly the key growth driver being the physical appearance and the current popular products are Vitamins A, C and E, coenzyme Q10, green chitosan, tea. burners. conjugated linoleic acid (CLA), grape seed extract, multi-vitamins,



calcium, gingko biloba, fish oil and lecithin. In Singapore, where consumers have higher purchasing power, the market is reported to be reaching saturation due to most of the distributors have multimarket presence as the vitamins and dietary supplements have OTC presence. In the other southeast countries like Indonesia, Vietnam and Philippines lower income groups still consider nutraceutical products a luxury whereas, health claims on nutraceutical products are not allowed in Malaysia, Thailand and Singapore. Manufacturers and distributors of nutraceutical products in this region face difficulty in communicating the health benefits to consumers and have a negative effect on their top line. The manufacturers need to emphasize on consumer awareness as well create brand awareness through extensive advertising and marketing. In Philippines the fortified food with vitamins and minerals are becoming a part of regular diet with government and NGO's increasing consumer awareness thus likely to increase the demand for nutraceuticals. In Taiwan nutraceuticals market is highly competitive with high marketing costs and labeling and advertising legislation applies in the country. Currently

the popular products include multivitamin, propolis, calcium, vitaminC, ginseng and herbal products. In addition, the manifold health benefits offered by nutraceutical products such as a sense of wellbeing, better performance in daily activities, preventive healthcare and improved physical appearance guarantee strong market growth in the region.

2.1.3.5 China

China's nutraceutical market is estimated at about USD14 billion in 2007. Strong economic growth leads to upgrading and diversification of functional foods, beverage, nutritional supplements and pharmaceutical production capabilities. The government policies have liberalised the restrictions on health food sales. This is also helping increase the demand for nutraceuticals products in China. Furthermore, the demand for dairy-based functional foods has been increasing in the country. An increase in medical costs and health consciousness are also driving the growth of the Chinese nutraceuticals market. Customer's decisions are mainly influenced by taste, convenience, style and also the benefits associated with nutrition, which plays a major role. Despite these growth drivers, there is no support for nutraceutical products. Negative publicity through media further affected the Chinese nutraceutical market. Moreover, intense competition and growing costs will challenge the new entrants in the market.

2.1.4 Outlook

Increasing health consciousness has been one of the most important stimulating factors for rapid global growth of the nutraceutical and functional food industry. The growth in nutraceuticals market is expected to be driven by the functional foods market, with high growth predicted in the vitamins, minerals and



supplements (VMS) sector in the coming years. The industry is likely to face stringent

regulations regarding the safety and efficacy of functional foods in the near future. As consumers become more health conscious, the demand and market for nutraceuticals and functional foods is likely to grow. Globally the nutraceuticals and functional food industry is estimated to reach to USD137 billion in 2009 as per Cygnus estimates growing at a CAGR of 6.8%. Soft drinks (fortified with natural nutrients and other health supplements) and dairy products are the fastest growing segment of the nutraceutical and functional food industry in the coming years. Potential markets for nutraceutical would be Gulf region especially UAE, Qatar, Oman and Kuwait. Among the major markets US will outpace every one and is estimated to reach to USD45.58 billion in 2009 growing at the rate of 34% followed by Europe at USD34.25 billion (25%growth rate) and Japan USD32.88billion growing at 24%. The Asian market is likely to grow at a higher rate thus having 35% in 2009 from a market share of 30% in 2007 as per the Cygnus estimates.

2.2 Indian market overview

2.2.1 Introduction

Nutraceuticals is an evolving segment in India. More and more pharmaceuticals, fast moving health goods (FMHG), OTC and fast moving consumer goods (FMCG) companies are entering into this segment. Companies are focusing on this segment mainly as preventive therapy rather than curative therapy. They have also realised that nutraceutical products can be supplement products for their therapeutic segment. Consumers are increasingly becoming health conscious and realising the importance of dietary supplements to help them deal with fast-changing lifestyle, which has put them at risk of diabetes, cholesterol, heart problems. Change in food habits has been one of the most critical consequences of changing lifestyle. Consumption of junk food, high calorie foods and lack of exercise leads to a number of diseases related to nutritional deficiencies. Nutraceutical products play a vital role in such a scenario.

Indian market is largely a prescription-oriented market. Many nutraceutical companies are trying to promote their products through the doctor. Companies are trying to convince doctors through e-newsletters and by conducting symposia to advice their patients to go for nutraceutical products.

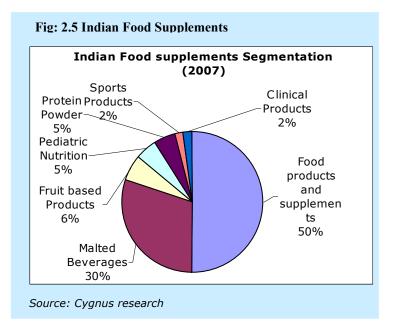
2.2.2 Market segmentation

Indian nutraceutical market is composed of food supplements and vitamins and mineral supplements. Food supplements include food products and supplements, malted beverages, protein powder, paediatric nutrition, fruit-based products, sports products, and clinical products; the segment is valued at INR11.25 billion in 2007. Vitamins and minerals include Vitamin-B complex, multivitamins, anti-oxidants, protein supplements, enteral nutrition, Vitamin-B12 and metabolites and Vitamin-C with minerals; the segment is valued at INR7.5 billion in 2007.

2.2.2.1 Food supplements

In food supplements, the major share is held by food products and supplements (artificial sweetener, meal replacer, and ginsengs), valued at INR5.63 billion in 2007. The next

major pie is held by malted (Horlicks, beverages Complan, Bournvita, Boost, and Red Bull), valued at INR3.38 billion. Boost and Horlicks are the top beverages brands growing in The nutraceutical sector. growth of these two products is mainly because of intense market research and product development activities, with



an improved formulation which is clinically tested to make children "Taller, Sharper, and Stronger" and also with new flavours like Chocolate Horlicks, Junior Horlicks and Boost Chocolate. The third major segment is fruit-based products (Real, Tropican), valued at INR0.68 billion. It is followed by Pediatric Nutrition (Lactogen, Lactodex, Dexaloc, Pediasure), valued at INR0.56 billion. Protein powder, sports products, and clinical products are valued at INR0.56 billion, INR0.23 billion and INR0.23 billion respectively.

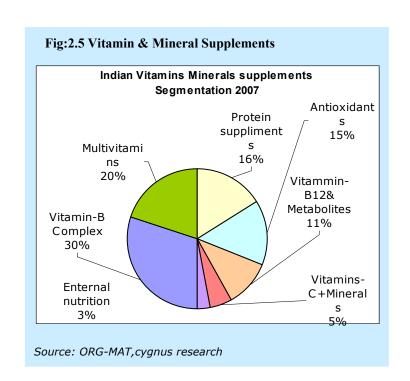
S.No	Type of Product	Leading Brand (s)	Company	Market size
1	Food products and	Sugar Free	Zydus Cadila	
	supplements	Dexrice	Wockhardt	INR5.63 billion
	(Artificial sweetener,			
	Meal replacer, and			
	Ginsengs.			

2	Malted beverages	Horlicks	GSK	INR3.38 billion
		Complan	Heinz	
		Bournvita	Cadbury	
		Boost	GSK	
		Red Bull	Red Bull GmbH	
3	Fruit based products	Real	Dabur	INR0.68 billion
		Tropicana	Pepsi Food Ltd	
4	Pediatric Nutrition	Lactogen	Nestle	
		Lactodex	Raptokes	INR0.56 billion
		Dexaloc	Wockhardt	
		Pediasure	Abbott	
5	Protein powder	Protenix	Dumex	
		GRD	Zydus	INR0.56 billion
		B.Protein	British Biologicals	
6	Sports products	Glucon-d	Heinz	
		Glucose-d	Dabur	INR0.23 billion
7	Clinical products	ORS		
		Revital	Ranbaxy	
		Electral	FDC	INR0.23 billion
Source:	Cygnus Research		<u> </u>	1

2.2.2 Vitamin & Mineral Supplements

Vitamins and mineral supplements market share is held by Vitamin-B complex, Multivitamins,

Antioxidants, Protein supplements, enteral nutrition, Vitamin-B12 and metabolites and Vitamin-C with minerals

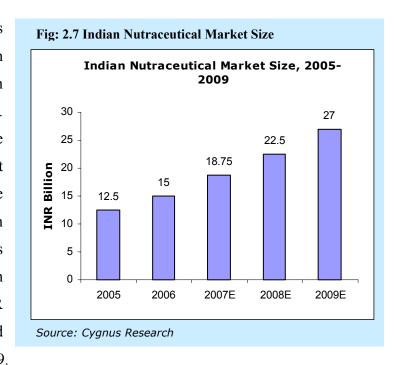


(see Fig 2.6). Major share is held by Vitamin-B complex valued at INR2.25 billion in 2007.

The next comes multivitamins valued at INR1.5 billion. The third major segment is protein supplements, valued at INR1.2 billion, followed by anti-oxidants, valued at INR1.12 billion. The anti-oxidants market is booming with products like fish oils (omega 3), Alpha Lipoic acid, COQ10. Interestingly, although Vitamin-B12 and metabolites occupies fifth place (valued at INR0.82 billion), it has grown very drastically over the year mainly because of health benefits like formation of RBC cells and maintenance of CNS and synthesis of amino acids. It is also involved in metabolism of fat, carbohydrate and proteins. It is followed by Vitamin-C with minerals and enteral nutrition, valued at INR0.37 billion and 0.22 billion respectively.

2.2.3 Market size

The word nutraceuticals has gained more importance in contemporary Indian healthcare market Nutraceutical market is in the initial stages of development and is growing at double digit. 2007, In Indian nutraceutical market estimated at INR18.75 billion and is growing at the CAGR rate of 21.23%; it is estimated to reach INR27 billion in 2009.



In India, nutraceuticals has attained greater importance for the industry. India has huge opportunity when it comes to ayurvedic, herbal and natural products in nutraceuticals. Nutraceutical Ayurvedic products like neem, tulsi, amla, psyillum, fish oil and brahmi

have been used over the years for various treatments. Currently, many Indian companies are conducting scientific research on these products.

Pharmaceutical companies are not the only players giving competition to nutraceuticals. It also faces tough competition from Hindustan Lever Limited (named as top advertisement spenders) and OTC companies, because they have high advertisement budgets and strong distribution channels. FMCG giants such as Hindustan Lever Limited (HLL), Nestle, Heinz, Godrej, and Amul are having their nutraceuticals products in the market. The market will evolve into a separate segment and new products will be introduced with specific indications of exact treatment of diseases. Indian nutraceutical market is expected to grow at higher percentage in coming years, with many more OTC, FMCG and pharmaceutical companies entering into the stream.

2.2.4 Outlook

According to Cygnus estimates, the nutraceutical market is estimated to reach INR27 billion in 2009, growing at the CAGR of 21.23%. Indian nutraceutical market is expected to be driven by food products and supplements segment. Increasingly, consumer focus will be on preventive therapy rather than curative therapy. The industry is likely to face stiff competition from domestic and international players.

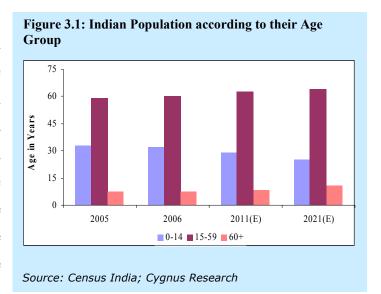
3. GROWTH DRIVERS

The nutraceuticals market, once viewed as largely a counter-cultural "back to nature" phenomenon, is being buoyed by a number of solid fundamentals and there is certainly room for the growth of the industry. The country is changing rapidly and today is a beacon of opportunity for the nutraceuticals industry. Despite the stall in growth, demand for self-medication and preventive medicine will continue to improve the outlook for nutritional supplements in the country. Consumers are also increasingly concerned about lifestyle-related diseases - mostly known in India which includes obesity, hypertension, and high lipid and blood sugar levels. Demographic factors like age group, per capita income, lifestyle, food habits and increase in diseases are the major growth factors on which the growth of health supplements depends.

3. I Aeging population

The converging economic and demographic trends in India have laid the groundwork for

opportunity in nutraceuticals. Currently the population pyramid in India has a wide base at the bottom from uncontrolled birth rates, and a small point at the top from lower-than-average life expectancies. However, because India is developing rapidly, life expectancies will increase. The ageing population will increase,



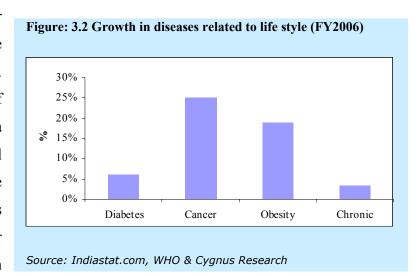
and demand for supplements and functional foods related to age-related conditions will certainly grow at double-digit rates. However the demand for products of middle-aged life needs, such as family-oriented multivitamins, infant formulas and healthy foods, will grow even faster than that. There are 516 million people between the ages of 20-55 today; that number will grow to 800 million in the next 40 years.

The increase in older age group population is altering the healthcare scenario in India. Ageing population, focus on preventive aspects will create new opportunities and drive healthy growth of pharmaceutical and nutraceutical companies. People are naturally looking forward to lead longer, healthier and more productive lives. This opens up new vistas for nutritional supplements as health consciousness within aging population impacts favorably, thus enhancing the growth of this segment. Higher growth of Indian economy can be attributed mainly to the higher number of working people in the Indian population. In FY2006, 60.38% of the total Indian population is within the working age group (15–59) that is so far showing a stable growth.

3.2 Changing lifestyle

Growth in Indian economy has been not only influencing and resulting in growth of income levels but it is also bringing a drastic change in the life-style of the Indian population mainly in the urban region. Urban population in India is growing at a drastic rate which is expected to increase from less than 29% of total population in 2006 to more

33% by 2020. A major issue of concern is the changing dietary habits. Increasing number of people are adapting to a high-fat, high-cholesterol diet, making them more prone to diseases. There is a sharp rise in the cancer and heart diseases in



India. Diseases that are related to the life-style of the people are showing higher growth. With rise in life style diseases like cancer, heart disease and diabetics, the spending pattern of anti-diabetic segment is growing at the rate of about 31%, while cardiovascular and CNS are growing at 17% and 11% respectively. According to World Health Organization (WHO), the long term ailment like diabetes is expected to encompass 57m

people in India. By the year 2015, it is predicted that in India cardiovascular diseases would replace infectious diseases as the major killer.

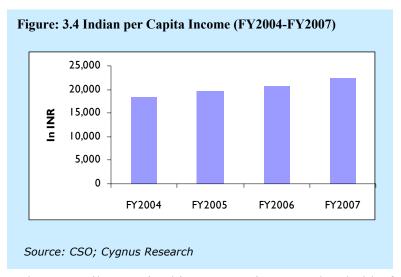
3.3 Increasing medical costs

Fastest life style disease segment such as Anti Diabetic segment, Cardio Vascular segment and Central Nervous System are driving the demand for multi-specialty and super-specialty healthcare services which in turn escalates the treatment costs. Exponential increase in expenditures within the health care system is forcing many consumers to seek out more cost-effective alternatives to those being provided by traditional forms of high cost professional and structured medicine. In the poorest countries, people with diabetes and their families bear almost the entire cost of whatever medical care they can afford. In Latin America families pay 40-60% of diabetes care costs out of their own pockets. In India, the poorest people with diabetes spend an average of 25% of their income on private care. Most estimates claim treatment costs in India start at around a tenth of the price of comparable treatment in America or Britain. Significant cost differences exist between USA, U.K. and India when it comes to medical treatment. India is not only cheaper but the waiting time is almost nil. This is due to the outburst of the private sector which comprises of hospitals and clinics with the latest technology and best practitioners. Today, all major transnational and large Indian pharmaceutical companies have ventured into nutraceutical products as they have realized that the future is for preventive therapy rather than curative therapy. Secondly, these products can also be supplementary products to their main products in therapeutic segments. Also, pharmaceutical companies having good access to doctors in India can make promotion of the products easier. The US is set to remain in its position as largest consumer because of the broad and increasing range of functional and nutraceutical products produced domestically.

3.4 High spending power

Working population of India is expected to reach 64.2% of the total population by FY2021, according to the projections constituted by The National Commission of Population, India. This will imply higher income level of people and their better ability to spend on health care products. Increase in literacy rates and awareness of medical information will lead people to use more medicines, being the costly component of healthcare.

Supplements are generally consumed in addition to the normal diet and as such are part of not the core spending on lifestyle essentials. There have been a number of studies that have shown that the spending distributions of disposable income in



developing countries does not change until countries hit a per capita GDP threshold of around \$5,000. Current disposable income per head in India, (in international dollar (\$) PPP terms) is \$2,303, but is expected to grow to \$3,033 by 2008. That means there is a growth potential of \$3.5 billion increase in the size of the nutraceuticals market in India in just three years. India is the second largest populated country in the world comprising 1.11 billion people. Indian population is expected to reach 1.38 billion by 2025 according to the Census, India. Growing population and particularly the growing share of the earning people is providing true growth opportunity to the Indian pharmaceutical industry. Increasing working population and the growth in the income levels, i.e. the per capita income will give a boost to health care and pharmaceutical industry in India.

3.5 Awareness of preventive medicine

Presently, all major transnational and large Indian pharmaceutical companies have ventured into nutraceutical products as the mantra for the future is for preventive therapy rather than curative therapy. Increasing urbanisation has brought about major changes in the lifestyle, making Indians prone to various conditions such as busy lifestyles, increasing stress levels and heavy dependency on junk, high calorie foods and lack of exercise, all lead to health problems. Further, increase in knowledge, higher spending power of people at large, information on the benefits of nutraceuticals and increasing health consciousness are factors that have led to the popularity of nutraceuticals. Awareness and focus on preventive therapy has also aided the increase in consumption of nutraceuticals. Consumers are increasingly becoming health-conscious and are realising the need for dietary supplements to help them cope with the fast-changing pace of life, which has put them at the risk of diabetes, cholesterol, heart ailments, arthritis and so on. With the Indian market being a largely prescription-oriented market, many nutraceutical companies are trying to promote their products through the doctors. With health complications on the rise and healthcare costs becoming more and more unaffordable, a time will definitely come when the Indian consumers would opt for preventive measures rather than spend a fortune on treatment

3.6 Baby Boomers

Baby boomers (those born between 1946 to1964) are the most important consumers to the industry, as their new attitudes towards disease prevention and are in one of the highest risk age groups for many diseases and illnesses. Despite advances in traditional medicine, many diseases such as diabetes, cancer and heart disease are on the increase, and consumers are examining with renewed enthusiasm the close link between diet and health. Health-conscious baby boomers are eating their way to a better life, fuelling a sharp rise in demand for functional foods or nutraceuticals. From margarines that lower cholesterol to yoghurt that strengthens the immune system, nutraceuticals are emerging as an attractive new business for food companies looking to boost sales and sharpen margins. The bulk of new food and drink products targeted at 'middle age' consumers,

have been directed at menopausal women which includes foods containing soy isoflavones, marketed to help ease the symptoms of menopause. The baby boomer generation will always opt for a dietary supplement over a drug if they believe it will work for them. There is lot more room for functional food and dietary supplement manufacturers to target baby boomers, but it will require the use of sensitive marketing tactics.

3.7 Increasing malnutrition led diseases

A growing number of developing countries must shoulder a double burden of malnutrition: the persistence of undernutrition, especially among children, along with a rapid rise in overweight, obesity and diet-related chronic diseases. The growing burden of non-communicable diseases (NCDs) in both developed and developing countries, and the associated rise in public health and social expenditures, were reviewed at a special session of FAO's(Food and Agricultural Organization of the United Nations) intergovernmental Committee on Agriculture (COAG) to provide governments with policy advice on nutrition and healthy diet to prevent NCDs, and requested a thorough assessment of the linkages between the diseases and changing food consumption patterns. According to new report by FAO's Nutrition and Consumer Protection Division (AGN) countries like China, Egypt, India, Mexico, the Philippines and South Africa the market trends over the past 20 years has shifted to diets high in saturated fat, sugar and refined foods. The report also highlighted the following trends:

- In India and Philippines the trends were as High prevalence of undernutrition in children and adults, emerging problems of overnutrition, diabetes and high blood pressure (mainly in urban areas) and continuing high prevalence of micronutrient deficiencies.
- In South Africa significant levels of stunting, but declining levels of underweight and wasting. In adults, overweight and obesity are more serious than underweight.
 There is rising incidence of cardio-vascular disease, diabetes and cancer, and of some infectious diseases, notably TB and HIV/AIDS.

• In China, Egypt, Mexico Both stunting and overweight was public health problems in children. Among adults, underweight is insignificant while prevalence of overweight is high or increasing. Infectious disease is declining, but diabetes and coronary heart disease are on the rise.

4. ISSUES AND CHALLENGES:

4.1 Intense competition

Competition for the Nutraceuticals products is from many sources, including Pharmaceutical companies, Fast Moving Consumer Goods (FMCG), Fast moving health goods (FMHG), companies that sell nutraceuticals products to supermarkets, large chain discount retailers, drug store chains and independent medical stores, health food stores, others who sell to wholesalers, and also mail order vendors, electronic commerce and network marketing companies. The competition is not only in domestic but also in international market.

On the other hand, pharmaceutical companies face a big challenge from nutraceutical market - one major challenge is that companies will be serious on this business over a period of time, secondly, that already companies are focusing into this market. Even more health market is flooded with different new terminologies like nutraceuticals, cosmeceuticals, Biopharmaceuticals, Herbaceuticals, Ayuraceuticals, Skinceuticals, Dermaceuticals, Nutri-cosmetics and countless. Among all these, Nutraceuticals has gained more importance and competition for the industry in India and abroad.

Even FMCG companies are more focusing into nutraceutical market where in Hindustan lever limited (HLL) company ventured into 'wellness' category with launch of dietary and food supplements products under its Ayush franchise and even company has recruited experts from Ayurvedic and pharmaceutical technologists, to develop relevant products because it has adopted principles of Pharma industry to evaluate their products clinically. Moreover Ayush franchise includes both personal care and health care range and into wellness sector. So growth in this sector have made other players like homegrown Pharma major Win-Medicare (UK Modi) and has signed a licensing and distribution agreement with US-based Nature's bounty to market and distribute its health supplements products in the country.

As a result there is increase in competition that has provided challenges for the pharma companies, FMCG, and FMHG companies to provide innovative product, product

positioning, aggressive promotion and distribution strategies in which they want to gain the major market share in nutraceuticals.

4.2 Functional Foods gains momentum

Nutraceuticals and Functional foods are basically different types of products. Functional foods may contain nutraceuticals, but they are complete foods similar in form to other, conventional foods, with which they compete in the marketplace. Nutraceuticals are consumed in medicinal form.

Functional foods are food components that provide physiological benefits, reduce the risk of chronic diseases and also provide basic nutritional functions. Functional foods are seemingly diverse products available including eggs, cereals and grains, nutritional bars, dairy products, and enhanced prepared and processed foods. Even consumers are taking time to read labels and comparing products, in which the companies claim about their credibility of products.

Consumer education increased, so the technological advanced within the industry. The advances in food technology and science are providing companies with sophisticated tools and resources, which should ultimately lead to increased growth within the industry. Today, new product development is rarely based on slick marketing gimmicks. Instead, scientifically proven claims and justifications are becoming required for success.

Mounting to the challenge, leading companies are setting a pattern of new standards, providing both the industry and consumers with food products and ingredients that deliver efficacious structure, palatable products, and pioneering delivery systems. The functional foods industry will continue to grow and evolve. With the expansion including technological advancements, a more permissive FDA, and an increasing consumer demand, the future promises to be interesting and exciting

4.3 Pharmaceutical and food companies join the bandwagon

Even though nutraceuticals are traditional close to pharmaceuticals, pharma companies are not the only players in the field. They have to face stiff competition from companies in the food and beverage industry. These companies are also entering into nutraceutical

market with their range of special foods for weight loss, diabetes, and beauty care, skincare.

Moreover these companies have huge advertising budgets and well established distribution channels that make them a strong in the market. On addition FMCG giants like Nestle, ITC, Cadbury's, Parle, Britannia, Heinz, Hindustan Lever, Godrej and Amul already have quite a few products in nutraceutical segment. In order to match up with these market competitions, pharma companies may have to follow the OTC in which they fire up promotions in order to capture a sizeable market share and to ensure brand recall.

In the pharma industry, Sugar Free, a product from the Zydus Cadila has deployed a different marketing strategy. It starts off from the unique yellow hour glass pack and ends with television commercials and other promotional activities that inform consumers about how the product can be used in various preparations other than tea or coffee. The marketing is a success and the brand enjoys a high recall among its target audience. Over a period of time, many pharma companies look for aggressive and innovative strategies to counter competition.

Pharma industry is growing with new product launches and entry of new players. With this competition even government also come up with new regulations. The market will evolve as a separate segment and new products will be introduced with specific indications for treatment of specific diseases.

4.4 Consumer awareness

In India consumer awareness of the nutraceutical products is very less as the industry is more believe based than evidence based. Innovative positioning and communication strategy ought to be adopted by the companies which will increase the equity of the nutra industry. Among the masses there is lack of awareness as only seven to eight percent people areaware, where as 82 percent are does not know what the word nutraceuticals meansthis is the basic challenge the industry has to face.

5. CRITICAL SUCCESS FACTORS

The surest way to grow the market for functional foods, nutraceuticals and dietary supplements is to prove they work. Efficacy is, after all, their Unique Selling Proposition. The critical successes factors include branding, pricing, market promotion and distribution channel which allow marketers to align their products with health-oriented causes, consumer and practitioner education and the all-important clinical trial.

5.1 Branding

The branding is difficult to create overnight because there must continued investment over a long period of time in order to remain in the market. Product branding is a process that builds a conceptual identity that will reflect a key message target the customers over a period of time. Branding functional ingredients is a long and costly process, according to many specialized manufacturers, but is worth it in order to stay competitive and ensure the long-term success of ingredients. The companies take the approach of combining cobranding, investment in research, and investment in public relations to ensure the brands appear via numerous channels. Nutritional supplement ingredient branding is expensive and requires a long-term commitment from the company. Research shows that the consumer's decision to purchase is determined by brand issues and will pay more for a leading brand compared to a weaker brand as they have above-average loyalty, enabling companies with strong brands. In the natural products and nutraceutical industries, building strong brand equity provide generating a greater projected income, increase cash flow by increasing market share and allowing premium pricing, and create an asset that can be sold or marketed by B2B customers. Launching a nutraceutical brand with a solid marketing campaign can often help to overcome potential pitfalls that may occur down the road and consumer market research helps in determining the direction a company needs to take to move a product forward. In the increasingly competitive nutraceuticals market, branding strategy is essential to market differentiation.

Co-branding of Ingredients helps suppliers and manufacturers reduce costs and enhance product credibility. Many ingredient suppliers and nutraceutical manufacturers adopt cobranding strategies to help them share the manufacturing and promotional costs. In such

an arrangement, ingredient suppliers acquire customers that buy exclusively from them, while nutraceutical manufacturers gain from the brand value of the ingredients. The nutraceutical products that contain branded and well-promoted ingredients sell at higher prices in the market.

5.2 Pricing

Most nutraceuticals are highly priced and hence the tag of exotic commodity remains in spite of awareness. Pricing has been one of the critical factors since in this market pricing is exorbitant though it (nutraceuticals) claims to reach the length and breadth of the population, the target consumers still remain the urban elite in India. The rural population of India uses products like chyawanprash and horlicks which in turn is a matter of placing the product as a necessity. But if the company is to make nutraceuticals as a part of monthly ration, price cuts are necessary so that they do not pinch the consumer's monthly budget. Pharma and Nutraceutical Companies should adopt the strategy to initially cut margins to make nutritional supplements affordable if they have to reach the majority of the people therefore breaking the price barrier. In order to sustain in the market where the nutraceuticals are basically marketed as OTC products there still lays an opportunity to reduce the portion of costs related to packaging, which allows companies to sell the same product at an even lower price to consumers. In developing countries like India, a small reduction in price does not necessarily mean reduced profits; instead it means significantly more volume from targeting a much larger base.

In the domestic front India is far more developed than Chinese counterparts in areas like fermentation processes, plant extraction and even chemical synthesis along with labour cost savings have enough room to reduce the pricing of the nutritional supplements and target the consumers at both urban as well as rural level. Some of the global nutraceuticals companies have discovered India as an incredible research and development resource, particularly stemming from the large and mature generic pharmaceuticals industry that exists in the country.

5.3 Market promotion

Where the success or failure of a commercial product depends on the efficacy or successful promotion of a key ingredient, it may be advantageous to coin the name of that ingredient in order to claim exclusivity in marketing and promoting the end product. A successful ingredient brand campaign can transform a commodity product into an enormously valuable consumer brand worth billions of dollars. Consumer advertising is expensive, but is always critical to the success of a branded ingredient. Again, manufacturers will often expect a supplier to assist in this process, since the resulting sales will generate increased purchases of branded raw materials and in effect lock a manufacturer into an extended relationship with the supplier. Nutraceutical players have to first prove that the benefits their products claim are more significant than home remedies, as nutraceuticals in India are part of home remedies. Companies have to adopt a segment-wise approach for promoting the products and target certain segments by tapping gyms, health clubs and dieticians who are increasingly playing a role in health decisions of the elite. Certain Companies also target working executives in their offices since they are most prone to lifestyle disorders from irregular eating, missing meals, eating junk food, smoking, drinking, daily office stress and lack of exercise. There are other potential consumers like women, adolescent girls and geriatric audiences. Pharmaceutical companies have an advantage in India as the promotion is done through doctors due to their well-established presence in the business. And since these companies have good access to doctors, the promotion of the products becomes easier. Once a doctor recognizes a nutraceutical that is manufactured by a renowned pharma company, it becomes a doctor recommended brand. Presently in the domestic front nutraceuticals are promoted through mainly medical field. These products are not patent driven and, hence, companies find it easy to launch products.

5.4 Channels

For nutraceutical companies with a unique ingredient, effective ingredient branding can facilitate market penetration in highly competitive distribution channels. Even though nutraceuticals are traditionally close to pharmaceuticals, pharma companies are not the only players in the field. They have to face stiff competition from FMCG companies and companies in the food and beverage industry. These companies have huge advertising budgets and well established distribution channels that make them a strong force to reckon with. In order to match up with these giant players, pharma companies have to follow the OTC example. They have to fire up promotions to capture a sizeable market share and to ensure brand recall. The direct selling nutraceuticals companies like Amway sell their products to distributors and who in turn sell to the final consumers. This company promotes individual entrepreneurship through its innovative direct selling approach of world class products and is the country's leading direct selling FMCGcompany. The market leader of Chyawanprash, Dabur rolled out its new initiative, Project 'DARE' (Driving Achievement of Retail Excellence), aiming to reorganize the distribution structure and influence the consumer at the point of purchase. The company has also adopted the direct selling model and is selling some nutraceutical products like Spirulina directly to consumers through home-to-home and chemist outlets. A better choice for the nutaceutical companies would be to develop strategic alliances with indigenous distributors and/or agents. Today's growing nutraceutical market and emerging interest among chemical wholesalers combines to provide a wide range of network distribution for the company which is one of the critical factors for the top line growth and sustenance in the market. Thus multiple communication channels to reach out to masses and hammering the brand can encourage the nutraceutical products to reach to the end user.

6. MAJOR PLAYERS

Introduction

Major players in this industry include, direct selling companies like Amway, Pharma MNCs like GSKCH, Ayurvedic companies such as Zandu, Dabur India, Himalaya Herbal Healthcare, domestic pharma companies like Ranbaxy, Elder Pharmaceuticals, Cadila Healthcare, Tablets India and other companies like British biologicals, E.I.D Parry India ltd and Raptakos, Brett & co. etc. Almost all companies have a wide range of nutrceutical products the market with the brand recognition in the nutraceutical segment. In the health goods segment lots of dairy manufacturing companies are also claimant for being considered as nutraceuticals manufacturing company; however they are excluded from the scope of major players section. Similarly some food manufacturing companies delivering various grades of food nutrients are also excluded from the discussion.

6. I Abbott India Ltd

6.1.1 Company Background

Year incorporated: 1965

Number of employees: 1000

Corporate structure: Public Ltd. Co.

Industry Segments					
Pharmaceuticals Ayurvedic Nutritional supplements					
✓		✓			
health care	OTC	Others			
✓	✓				

Company overview

- Founded in 1888 by a young Chicago physician, Dr Wallace Calvin Abbott, the company has evolved into a diversified health care company.
- The company is a global, diversified health care company, which manufacture and market pharmaceutical, diagnostic, nutritional and hospital products.
- The company provides healthcare solutions through its four business units:
- Primary Care, which markets products in the areas of Pain Management, Gastroenterology, with well-known brands like Brufen, Digene, Cremaffin.
- 2. Specialty Care Metaboloics & Urology provides solutions in the areas of Thyroid, Obesity, Diabetes and Benign Prostratic Hyperplasia.
- 3. Specialty Care Neuroscience has a varied portfolio, with specialty products in the Neurology and Psychiatric segments.
- 4. Hospital Care, offers products in the field of anesthesiology and neonatology namely Forane, Sevorane and Survanta.

6.1.2 Contact Address

Registered Office Address:

3-4 Corporate Park, Sion -Trombay Road Mumbai Maharashtra Pin Code 400071

Tel. No. 022-67978888 Fax No. 022-67978727

Email: webmaster@abbott.co.in Internet: http://www.abbott.co.in

6.1.3 Management Team

6.1.3.1 Board of Directors

Munir Shaikh Chairman / Chair Person

He is a Fellow of The Institute of Chartered Accountants in England and Wales and also Director on the Board of Abbott Laboratories (Singapore) Pte Ltd, Abbott Laboratories (Pakistan) Limited and Pt Abbott Indonesia. He Joined Abbott in 1968, and has since served in several management positions.

Vivek Mohan - Managing Director

He joined the company in 1992 as Product Specialist for Abbott Diagnostics Division. In 1995 he joined Abbott international. Mr. Mohan has 12 years experience with Abbott Laboratories at various affiliates.

Directors

S Jain

He leads Abbott's marketing team since 1998. He has rich and varied experience in the areas of managing strategic alliances, brand acquisitions, sales force restructuring and deployment, distribution product portfolio rationalization.

Mario Durante

He has extensive knowledge in the areas of manufacturing. He joined Abbott in the year 99 and has held various senior management positions and has been in charge of various manufacturing operations worldwide.

Ranjan Kapur

He is an ex-citi banker. He is a veteran of the advertising business having spent 40 years with Ogilvy and credited with its turnaround and accelerated growth.

6.1.4. Products

The company provides pediatric products for infants and children, as well as for adults and people with special dietary needs.

Product	Therapeutic			
PediaSure	Pediatric nutritional formula			
Ensure	Adult nutritional supplement			

6.1.5. Business Strategy & Competitive Advantages

6.1.5.1 Strategies

- The company on an ongoing basis interacts with Abbott Laboratories Intl Co, USA, for technical expertise for products of high technology and pharmaceutical formulations in order to improve its quality of the products in the domestic market.
- The company has the strategy to partnership so as to consolidate its market position.
 - The company taps its global wide range product portfolio to launch in Indian market such that the products contribute to the bottom-line.
 - A significant proportion of the growth comes from organic means driving increased volumes by revitalizing growth in the core brands

6.1.5.2 Competitive Advantages

 The company's recent innovations include the addition of fatty acids known as DHA and ARA to build strong minds, along with unique fat blends that help a baby's growing body absorb calcium more effectively is one of the core competences.

6.1.6. Financial Details

6.1.6.1 Revenue

P& L items (INR m)	2004-05	2005-06	2006-07			
Net Sales	4,050.7	4,446.7	5,102.4			
Other Income	520.0	148.6	205.3			
Total Income	4,570.7	4,595.3	5,307.7			
Expenditure	3,152.8	3,684.1	4,387.7			
Operating Profit	1,417.9	911.2	920.0			
Interest	1.7	0.2	1.2			
Gross Profit	1,416.2	911.0	918.8			
Depreciation	41.7	39.9	44.4			
Profit before Tax	1,374.5	871.1	874.4			
Tax	352.0	279.5	275.8			
Profit after Tax	1,022.5	591.6	598.6			
Net Profit	1,022.5	591.6	598.6			
EPS (INR)	66.9	38.7	39.2			
Balance sheet Items	2004-05	2005-06	2006-07			
Equity Capital	152.8	152.8	152.8			
Reserves		2011.6	2305.3			
Source: company website, Cygnus research						

6.1.7. Outlook

- Company is the global leader in infant's nutritional products which is venturing into partnership in India in the coming year.
- Having a wide range of nutraceutical products globally, the company has immense oppututnity to cater the global products in India especially in nutraceuticals division.

6.2 Dabur India Ltd

6.2. I Company Background

Year incorporated: 1936 (listed) Corporate structure: Public Ltd. Co.

Industry Segments						
Pharmaceuticals Ayurvedic Health Care supplements						
✓	✓	√				
Consumer care	OTC	Others				
✓	✓					

Company overview

- Dabur India Ltd. (DIL) along with its subsidiaries (collectively known as group companies) is a FMCG Company with its business interest spread across the Globe made its beginning with a small pharmacy established by Dr. S K Burman at Kolkata in 1884.
- The company was incorporated on 16th September 1975 with the object of manufacturing and marketing FMCG, Ayurvedic & Pharmaceutical products.
- The company has 13 ultra-modern manufacturing units spread around the globe and six States of India. The group companies having manufacturing facilities in seven countries, namely India, Bangladesh, Nepal, Dubai, Sarjah, Egypt & Nigeria. Major markets of the group include India, Middle East, Nepal, Bangladesh, USA, and UK.
- The company is a leading consumer goods company in India with a turnover (consolidated) of INR22.33 billion (FY07)
- It has 2 major strategic business units (SBU) Consumer Care Division (CCD) and Consumer Health Division (CHD)
- The company has 3 Subsidiary Group companies Dabur Foods, Dabur Nepal and Dabur International and 3 step down subsidiaries of Dabur International - Asian Consumer Care in Bangladesh, African Consumer Care in Nigeria and Dabur Egypt. Company's Products are marketed in over 50 countries

6.2.2. Contact Address

Registered Office Address:

8/3, Asaf Ali Road, New Delhi-110002 Ph: 011-23253488

Corporate Office

Dabur India Limited,

Dabur Tower,

Kaushambi, Sahibabad, Ghaziabad - 201 010

(U.P.), India

Tel: 0120 – 3982000, 3001000

Fax: 0120 – 4374935 Website www.dabur.com

6.2.3. Management Team

6.2.3.1 Board of Directors

Mr V C Burman Chairman

B Sc in Business Administration was born in 1937 and joined the Board in 1979. He is the Promoter and the Chairman of the Company.

Dr. Anand Burman Vice Chairman

M.Sc., Ph.d. (University of Kansas, USA) was appointed as a member on the Board in 1986. He is the promoter Director and currently holds the Vice chairman's position on the Board of Directors.

Mr. Pradip Burman Director

B.Sc (Mech. Engg.) MIT (USA) and joined the Board in 1979. Currently he is the Whole time-Director of the Company.

Mr Amit Burman Director

MBA (Cambridge University, England) and was appointed as a member on the Board in 2001. He is the Promoter Non-Executive Director of the Company

Mr. Sunil Duggal Director

M.B.A. (IIM, Kolkata) and joined the Board in 2000. He is currently the Chief Executive Officer of the Company.

HH Maharaja Gaj Singh Director

M.A. (Oxford) joined the Board in 1993. He is the chief patron of certain renowned educational societies.

Mr. P N Vijay Director

Post Graduate from IIT, joined the Board in 2001. He is a leading expert in stock market.

Dr. S Narayan Director

He is retired IAS, and has done M.Sc. Physics, Master in Business Management (Finance), M.Phil in Development Economics from Cambridge University- UK and Ph.d from IIT Delhi.

6.2.4. Leading brands

- **Dabur** The Health Care Brand
- Vatika-Personal Care Brand
- **Anmol** Value for Money Brand
- **Hajmola** Tasty Digestive Brand and Dabur Amla, Chyawanprash and Lal Dant Manjan with Rs.100 crore turnover each
- Vatika Hair Oil & Shampoo the high growth brand
- Strategic positioning of **Honey** as food product, leading to market leadership (over 40%) in branded honey market
- Chyawanprash the largest selling Ayurvedic medicine with over 65% market share.
- Hajmola tablets in command with 75% market share of digestive tablets category
- **Dabur Lal Tail** tops baby massage oil market with 35% of total share and over 1.5 million retail outlets all over India

6.2.5. Business Strategy & Competitive Advantages

6.2.5.1 Strategies

The company's business strategy are given below

- In the year 2005-06 the company did an extensive print campaign to educate consumers about the holistic benefits of consuming Chyawanprash which belonged to health supplements of consumer care division being the flagship product of the company. The company's strategy on focused advertising has helped to increase its market share (in this category) from 60.9 %to 62.6 %.
- On the distribution side, the Company has rolled out its new initiative, Project 'DARE' (Driving Achievement of Retail Excellence), which aims to reorganise

the distribution structure to meet the needs of an evolving business environment and, thereby, to influence the consumer at the point of purchase.

- The key elements of DARE programme are:
- 1. The company recognized principles key segments in urban markets as wholesale trade, grocers, chemists, and organised retail.
- 2. Key customer segments were activated through strategic programmes such the 'Dabur Kings' wholesale programme that targeted key wholesalers across the country.
- 3. The Company identified rural focus states in the country in order to improving distribution reach, developing innovative trade promotions and creating novel packaging solutions and the opportunity was further leveraged through the programme, 'Dabur Apnaao, Lakshmi Laao' in all rural markets.
- 4. The Company emphasized on the brand building with endorsement of film stars for its products.
- The company amalgamated three subsidiary companies of Balsara Group of companies namely Balsara Hygiene Products Limited, Balsara Home Products Limited and Besta Cosmetics Limited took place during the year 2006-07 in order to strengthen market position as Balsara had wide products portfolio targeting the middle income group in the market.
- There were significant innovations in packaging and enhancing manufacturing capabilities and quality of the products so as to keep pace with the competitors in the FMCG market.
- By increasing its product portfolio, leveraging its brand value as an herbal specialist and strategically positioning its products, the Company believes that it will largely de-risk itself from pricing pressures and segmental contractions.

6.2.5.2 Competitive Advantages

 On the products side, with its strong heritage and positioning in Ayurveda, the Company has created a niche for itself with its offerings, and maintained steady rates of growth.

- During the year, the company launched Dabur Chyawanshakti, a unique mix of 47
 herbs and natural ingredients like draksha, ashwagandha and kesar. This health
 supplement is targeted at working adults to help them tackle work related stress
 and pressures of their daily lifestyle.
- The new advertisement campaign featuring Amitabh Bachchan and Vivek Oberoi promoting the products to the markets in order to remain market leader in flagship products.

6.2.6. Financial Details

6.2.6.1 Revenue

P&L Items (In INR millions)	2004-05	2005-06	2006-07	CAGR%
Sales (net)	12,310.9	13,455.0	17,451.5	19.1
Raw Materials Cost	5,546.8	5,781.9	8,004.6	20.1
Raw Materials cost on Sales (%)	45.1	43.0	45.9	0.9
Employee Cost	820.9	983.1	1,186.6	20.2
Employees Cost on Sales (%)	6.7	7.3	6.8	1.0
Selling & Administration Cost	3,631.5	3,614.0	4,561.1	12.1
Selling & Administration Cost on Sales (%)	29.5	26.9	26.1	-5.9
PBDIT	1,882.8	2,439.1	3,171.3	29.8
Depreciation	171.0	190.5	219.8	13.4
Interest & Financial Charges	46.6	57.3	44.3	-2.5
PBT	1,649.8	2,150.8	2,841.0	31.2
Tax	170.0	257.8	321.5	37.5
PAT	1,480.2	1,890.8	2,520.8	30.5
EPS (INR)	5.2	3.3*	2.92*	-24.8
Balance Sheet Items	2004-05	2005-06	2006-07	CAGR%
Share capital	286.4	573.3	862.9	73.57762
Fixed Assets (Gross Block + Capital WIP)	1,916.0	1,988.3	2,390.4	11.69598
Total Debt	486.0	205.0	200.0	-35.85
Net Working Capital	-702.0	-229.0	403.0	

^{*}During the year, the paid up share capital of the company has increased consequent upon the issue of bonus shares

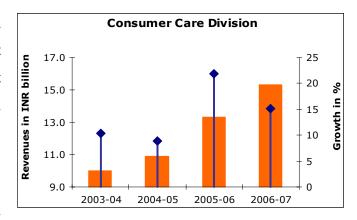
Source: company website ,Cygnus research

^{*}the Company has issued equity shares of Re 1/- each by way of allotting One Bonus Share against each share held by a shareholder.

FINANCIAL PERFOMANCE

CONSUMER CARE DIVISION

The Consumer Care Division (CCD) caters to six distinct segments of the FMCG market Hair Care, Oral Care, Health Supplements, Digestives, Home Care, and Skin and Baby care.



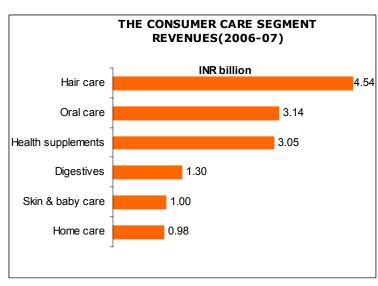
Source: Cygnus Research, Annual report

Driven by buoyancy in the FMCG market and a strong performance

by key brands, revenues from this division are the main revenue driver of the company. The company has shown 22% growth in 2005-06 basically due to the acquisition of the Balsara in the oral care and the home care segments.

Financial performance for 2006-07

In its traditionally strong Chyawanprash market, the Company has further strengthened its market share by achieving the highest growth in the segment in 2006-07 almost 15 % as compared to the 11.2 %of the industry. The health supplement category grew by 19.5 % in 2006-07 becoming 21.7 per cent of the CCD portfolio.



Source: company website, Cygnus research

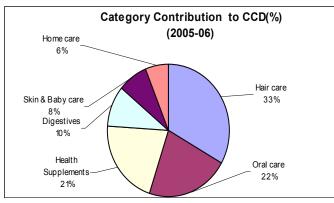
The three main constituents of this

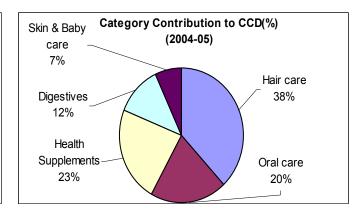
segment — Chyawanprash, Glucose D and Honey — recorded strong growth.

• The Company's flagship product, Dabur Chyawanprash, grew by 20.3 % to INR.1,690 million in 2006-07. Brand ambassadors Amitabh Bachchan and Vivek

- Oberoi were used in a new campaign that focused on bringing out the relevance of the product and educating the consumer about the benefits of Chyawanprash
- The category Glucose is also a seasonal product, recorded a healthy growth of 26.9 per cent to touch sales of almost INR.400 million in 2006-07. This is particularly creditable for a product that relies largely on advertising to build the brand.
- In honey, Dabur is the largest branded player. During 2006- 07, revenues from Dabur Honey increased by 15.4 per cent touch INR800 million. There is, however, a very large unbranded segment which can be further tapped by the Company.

Financial performance for 2005-06





Source: company website, Cygnus research

- The company recorded highest growth in 2005-06 of 22% in this division due the acquisition of Balsara products in the oral care and the home care segments, which account for 12 per cent of total sales of CCD. The Health supplement category recorded a healthy growth of 15 per cent.
- Sales of Dabur Chyawanprash, which in value terms is the largest product in this
 category, grew by 11.8 per cent in 2005- 06. This flagship product was promoted
 by a new advertisement campaign featuring Amitabh Bachchan and Vivek
 Oberoi.
- Dabur Honey also witnessed good growth of 9.4 per cent. Dabur Glucose increased by 40 per cent in value terms and gained significant market share.

6.2.7. Outlook

- The company plans to enter the high growth retail market in India through a wholly owned subsidiary, H&B Stores Limited (under incorporation). Under the plan the Company will invest INR 1.40 billion by 2010 to establish its presence in the retail market in India with a chain of stores on the Health & Beauty format.
- The company, with its new Chyawan Junior, has entered the milk beverages industry, valued at INR 15 billion. This segment is expected to grow at 15% in 2007-08, and the launch of Chyawan Junior would help Dabur establish a prominent position in the market.
- Dabur adopts kiranas as part of its Parivaar (a new initiative), to partner neighborhood shops by offering higher margins to drive volumes in the highly competitive FMCG segment. The number of Parivaar outlets is estimated to reach 12,000 to account for 8% of the company's consumer care division sales. The company aims to generate revenues of up to INR 1,200 million in the CCD segment from about 12,000 grocery stores across the country by the end of 2007-08.

6.3 Elder Pharmaceuticals Ltd

6.3.1. Company Background

Year incorporated: 1983	Corporate structure: Public l	td

Industry Segments						
Pharmaceuticals	Health Care supplements					
✓		✓				
Consumer care	OTC	Others				
	✓					

Company overview

- Elder Pharmaceuticals Ltd. (EPL) was promoted in 1983 by Chairman and Managing Director, Shri Jagdish Saxena.
- The promoters held about 36% of the equity as on September 30, 2006.
- Principal activities of EPL include manufacturing and marketing of pharmaceutical drugs, health care products, surgical and medical devices and consumer products.
- EPL has manufacturing and marketing alliances with 32 multinational pharmaceutical and health care companies and has Exclusive Marketing Rights (EMRs) in India for some of their products.

6.3.2. Contact Address

Registered Office Address:

Elder House, C-9, Dalia Industrial Estate, Off New Link Road, Andheri West Mumbai -400 053 India

Tel: 91-22-26730058-67 Fax: 91-22-26730054

Website--www.elderindia.com

6.3.3. Management Team

6.3.3.1 Board of Directors

Mr. Jagdish Saxena - Chairman& Managing Director

Having a Bachelor of Science degree has spent over 33 years working in the pharmaceutical industry.

Mr. Vijay N. Paranjpe - Joint Managing director

A Chartered Accountant and a Law Graduate by qualification, has worked with American Express Bank as its Head of Treasury (India) and as its Region Head.

Dr. Joginder Singh Juneja - Non-Executive Director

Aged 65, M.B.A. from the University of Oregon, USA and a Ph.D in Applied Economics from the University of Mumbai.

Dr. Sailendra Narain - Non-Executive Director

Aged 63, Dr. Narain holds a post graduate degree in economics and sociology

Mr. M.V. Thomas - Director (Finance)

A Chartered Accountant by qualification one of the founding Directors of the company.

Mr. Alok Saxena - Whole Time Director - MBA, PDM

Mr. Alok Saxena, 38, holds a number of memberships of professional bodies from India and abroad

6.3.4. Leading brands

Brands	Current sales (2006-07)(INR m)	Market share%	Therapeutic segment		
Shelcal	700	31	Calcium Supplement		
Chymoral	267	81	Wound Healing Enzyme		
Eldervit	147	40	Vit B12 Injectable		
I-Vit	25	2	Antioxidant		
Amifru	85	52	Ant-hypertensive		
Carnitor	85	42	Cardiovascular		
Formic	73	3	Anti bacterial		
B-Long	27	65	Nutritional		
Tiger	120	6	Pain relief balm		
Fair One	200	2	FMHG		
Source: company website ,Cygnus research					

Flagship brand

Shelcal

- Shelcal, with revenues in FY'07 of INR 700m and INR 830m (past 10months of FY'08) as per primary information given by the company information, is the largest selling calcium supplement in the INR 2.3bn domestic market. Being quasi-OTC it enjoys a strong brand loyalty, by working on a strategy which offering multiple dosage forms and wide penetration including rural areas. Shelcal is far ahead of its competitive brands like Calcium Sandoz of Novartis and Ostocalcium by GSK, in market share and revenue generation.
- Currently the company sales of B-long the nutritional supplement for FY'08(10months) is INR 70m and likely to up by the end of the financial year.

6.3.5. Business Strategy & Competitive Advantages

6.3.5.1 Strategies

- The Company's competitive strategy is to enter in niche segments which are growing at a healthy rate and launch high value products in domestic market by procuring EMRs from leading global pharmaceutical companies.
- The company's strategy to drive the topline lies in introduction of new products,
 acquisition of EMR for internationally known brands and effective market

- penetration for its products which command acceptance because of their quality and recognized brand name.
- The company has strong international growth strategy called the Global Girdle Strategy with which it has strong foothold in EU region
- Company has charted a strategy of an aggressive scheme of acquisitions, inlicensing of products and selective forays into niche therapeutic areas such as wound care, women's healthcare and nutraceuticals.
- The company plans to grow organically as well as through acquisitions, both within and outside India. Taking a step to enter the regulated markets of Europe and then USA acquired a 20%stake in London based NeutraHealth plc (an AIM (LSE) listed company). This acquisition offers an established platform for rolling out company's products through all its key channels to the European nutraceutical market.

6.3.5.2 Competitive Advantages

- The company has expertise in mass scale distribution of its products.
- Wound care, women's healthcare and nutraceuticals are the key therapeutic areas
 of the company
- The acquired company NeutraHealth has strong market positions in the vitamins, minerals and supplements sector of the UK and covers all the aspects of the distribution channels viz. ethical (doctors), large format retails stores, independent retailers and direct to consumer.
- The company focuses on niche products and excise duty benefits arising out of manufacturing set ups in Uttaranchal (SEZ) has also contributed to the growth of the company.

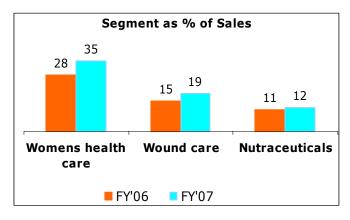
6.3.6. Financial Details

6.3.6.1 Revenue

P&L Items (In INR millions)	2004-05	2005-06	2006-07	CAGR%	
Sales (net)	2817.37	3508.31	4473.11	26.00	
Raw Materials Cost	1696.30	1849.42	2058.33	10.16	
Raw Materials cost on Sales (%)	60.21	52.72	46.02	-12.58	
Employee Cost	323.83	444.38	609.89	37.24	
Employees Cost on Sales (%)	11.49	12.67	13.63	8.91	
Selling & Administration Cost	364.40	497.40	651.60	33.72	
Selling & Administration Cost on Sales (%)	12.93	14.18	14.57	6.13	
PBDIT	484.20	665.20	854.70	32.86	
Depreciation	39.22	61.59	89.32	50.91	
Interest & Financial Charges	114.10	110.77	132.62	7.81	
PBT	302.50	487.38	668.21	48.63	
Tax	85.00	110.00	100.00	8.47	
PAT	217.50	377.38	568.21	61.63	
EPS (INR)	13.60	21.60	30.60	50.00	
Balance Sheet Items	2004-05	2005-06	2006-07	CAGR%	
Share capital	160	175	186	7.77	
Fixed Assets (Gross Block + Capital WIP)	638	899	1403	48.32	
Total Debt	1246	1871	2263	34.76	
Net Working Capital	1860	2172	2347	12.32	
Source: company website ,Cygnus research					

FINANCIAL PERFOMANCE

• During FY'06, Formulation segment contributed 81% of total sales which were driven by women health care segment (28% of total sales) Wound care (15% of total sales), Nutraceuticals (11% of total sales) and others. Contribution to sales from the API segment



Source: Cygnus Research

significantly came down to around 4 % from 22% on account of management's deliberate effort to shift focus away from low margin API products.

- Better product mix; reduction in low margin API business and better control of costs by prudent material management, has led to an increase in PBILDT by 44% YoY during FY'06.
- During FY'07, The Women's Healthcare division is the biggest contributor, accounting for 35% of Elder's total revenues. Other mainstays of Elder has been nutraceuticals as well as wound care segment which cumulatively garner 31% of totals sales. Elder has been however investing aggressively into other therapeutic area like life style diseases whose incidence in India in growing geometrically.
- Sixty-five per cent of our turnover comes from 10-12 brands. To list a few: calcium supplement Shelcal, wound healing product Chymoral, vitamin supplement Eldervit, cerebral disorder product Somazina, antihypertensive Amifru, Shelcal (All line extensions and associated brands) alone contribute to about 30 per cent of the turnover while others average 5-8 per cent.

6.3.7 Outlook

- Nutraceuticals is a very sought-after sector so the company would be able to distribute NeutraHealth's products in all the countries where it has its presence. It also plans to manufacture the same products for NeutraHealth at cost-effective prices from company's existing manufacturing plants in India.
- With the acquisition of Biomeda and a strategic stake in Neutralhealth, the company has gained a strong foothold in the EU. Further may strengthen its presence in other major markets, namely, Spain, Germany, Italy and France.
- The company has protein supplements in their product pipeline which they are proposing to launch in the coming year.
- The company is targeting the product shelcal the calcium supplement being the flagship product to reach sales of 1 billion in FY08.

6.4 E.I.D.-Parry (India) Limited

6.4.1. Company Background

Year incorporated: 1961 Corporate structure: Part of Murugappa group

Industry Segments				
Pharmaceuticals	Ayurvedic Health Care			
		supplements		
		✓		
Consumer care	OTC	Others		
		✓		

Company overview

- Established in the year 1788, Parry is presently engaged in a wide galaxy of diversified activities. It became a member of the Murugappa group in the year 1981
- The company is into Ceramic & Sanitary ware Sugar, Bio-Products & Chemicals – Sugar, Alcohol, Power, Bio-products and very recently into Nutraceticals.
- The Nutraceuticals division which became a part of E.I.D. Parry from 1st September
- 2006 continues to grow in all markets and its products are currently exported to 35 countries.
- Spirulina continues to be in the forefront in the nutraceuticals business has the highest number of certifications in the world. E.I.D.
- Parry, the only company in the world with dedicated R & D for all the three types of algae, is expected to outperform competition in the business for the years to come.
- With increasing medical care costs and aging population in the west, nutraceuticals as a category of preventive health care is bound to grow at a steady pace.

6.4.2. Contact Address

Registered Office Address:

Dare House, Parrys Corner, Chennai - 600 001

Tel: +91- 044 -2530 6789 Fax: +91-044 -2534 1609 Web site: www.eidparry.com

6.4.3. Management Team

6.4.3.1 Board of Directors

A. Vellayan Chairman

He holds a diploma in Industrial Administration from Aston University, Birmingham, U.K. and Masters in Business Studies from the University of Warwick Business School, U.K. He has industrial experience of about 26 years

P. Rama Babu Managing Director

He holds a Masters degree in Social Work and Labour Welfare and has played a key role in the turnaround of the company's expansion and acquisitions.

Anand Narain Bhatia

He was educated at Delhi University and Cambridge in Economics and joined Hindustan Lever (HLL) in 1970 worked in both Brand and Sales Management

S. B. Mathur

Mr. S. B. Mathur is a Commerce Graduate and a Fellow Member of the Institute of Chartered Accountants of India took over as Chairman of Life Insurance Corporation of India in August 2002 and retired in October 2004.

R. A. Savoor

B.Sc. Tech. He has 34 years of experience, of which 12 years as Chief Executive and

Sebastian K. Thomas

Chief Executive (Nutraceuticals)

6.4.4. Products

• The Division currently produces 3 different types of micro algae, Organic Spirulina, Dunaliella (Natural Mixed Carotenoids) and Haematococcus (Astaxanthin) at its Oonaiyur facility.

6.4.5. Business Strategy & Competitive Advantages

6.4.5.1 Strategies

- The company's strategy is to widen its market not only in India but also worldwide.
- The nutraceuticals products are currently exported to 35 countries. Organic Spirulina, the main product made forayed into New Zealand and the company has also tried to enter into Cosway, Malaysia
- The company's strategy is to enter into Hi profit Hi growth sectors of international business.

6.4.5.2 Competitive Advantages

- The Organic Spirulina produced by the Company is the most certified Organic Spirulina in the world with 5 quality certifications and 3 Organic Certifications to its credit.
- The Organic Spirulina of the division was certified to meet stringent standards such as US Pharmacopeia, USDA and Naturland Germany.
- Organic Spirulina, the main product of this business continue to outperform competition in its segment.

6.4.6. Financial Details

Nutraceuticals division		
Business Established:	March 2000	
Merged with EID Parry	1st Sep 2006	
Revenues from 1st Sep 06 to 31st Mar 07	INR 111.2 million	
Proportion of Company's total Income	2%	
Exports	INR 90.7 million	
Source: company website ,Cygnus research		

6.4.6.1 Revenue

Financial Performance			
Details 2006-07 (7 months)	(INR millions)		
Revenue	111.2		
EBIDT	17.1		
EBIT	13.0		
Capital employed 240.3			
ROCE 5%			
Source: company website ,Cygnus research			

6.4.7. Outlook

- The nutraceuticals Division has emerged as a global leader in Organic Spirulina business and is continuing with its R&D efforts to research new strains of algae to widen its product basket in coming year.
- Two new strains of Algae were successfully experimented in small scale for commercial production of Omega 3 EPA and DHA. Additional ponds have been built to expand and commence limited commercial production. The products from these Algae would cater to heart health and brain health and is expected to hit the market in the 2nd half of the FY 2007-08.
- Since 82% of the current revenue is from exports, adverse fluctuation in dollar prices will impact the revenues of the division in coming two to five years.

6.5 GlaxoSmithKline Consumer Healthcare Ltd

6.5.1. Company Background

Year incorporated: 1958

Number of employees: 2700

Corporate structure: Ltd. Co.

Industry Segments				
Pharmaceuticals	Ayurvedic Health Care supplements			
✓				
Consumer care	OTC	Others		
✓	✓			

Company overview

- GlaxoSmithKline Consumer Healthcare Ltd (GSKCH) is an Indian associate of GlaxoSmithKline plc, UK.
- GSKCH is one of the largest players in the health food drinks industry in India.
- The company has its manufacturing plants located in Nabha, Rajamundry and Sonepat has a total workforce of 2,700 people.
- Its flagship product, Horlicks is a brand since 100 years in India.
- GSKCH has a strong marketing and distribution channel with over 1800 wholesalers and direct coverage of 400000 retail outlets.
- Mothers Horlicks was launched catering pregnant and breast feeding women in 1997.

6.5.2. Contact Address

Registered Office

Patiala Road

Nabha 147201 (Punjab)

Head office

DLF plaza tower

DLF phase I,

Gurgaon

Pin 122002

Haryana

Tel. 0124-2540700/5057700

Fax: 0124-2540720/2540721

Website--www.gsk-ch.in

6.5.3. Management Team

6.5.3.1 Board of Directors

Chairman

Mr TSimon J. Scarff, O.B.E

He is currently the Non Executive Chairman of GlaxoSmithKline Consumer Healthcare Limited. Simon Scarff started his career at Horlicks Limited, UK (now part of GlaxoSmithKline plc).

Managing Director

Mr Zubair Ahmed

He has thirty years of experience in the Fast Moving Consumer Goods (FMCG) sector.

Directors

Mr.Ashok Dayal

He is presently a Non Executive Director and was the Executive Director of Deutsche Bank in India, Pakistan, Sri Lanka, Thailand, Indonesia and Vietnam.

Mr Kunal Kashyap

He is a Chartered Accountant and is currently the Chairman and Managing Director of Allegro Capital Advisors Pvt Ltd, a leading Investment Bank.

Mr P. Dwarakanath

Mr. P. Dwarakanath presently the Director - Human Resource of the Company has over 34 years of experience in Engineering, Chemical, Pharma and Consumer Goods industry.

Mr P. Murari

He joined the Indian Administrative Service (IAS) and has held many distinguished positions, including Sub-divisional and District Magistrate, Deputy Director of Census Operations.

Mr Praveen K. Gupta

He joined this Company in 1975 and has held positions in Finance, Procurement, Materials Management, and Supply Chain Management.

Mr Subodh Bhargava 65

He holds a degree in Mechanical Engineering from the University of Roorkee

6.5.4. Products Portfolio

Consumer healthcare segment	Products Brands
Nutritional	Horlicks
	Boost
	Maltova
	Viva
OTC	Crocin
	Eno
	Iodex
Vending	Horlicks vending
	machine

6.5.5. Business Strategy & Competitive Advantages

6.5.5.1 Strategies

- The company's topline growth largely depends upon the growth of flagship products such as Horlicks and boost. The company adopts the strategy to aggressively invest in these brands in order to enhance the topline.
- The company's strategy is to invest in manufacturing plants, new R&D projects and product innovation so as to strength its position as a key FMCG company in India to watch out for.
- Attractive state of the art packaging for junior Horlicks and propelled its growth rate by 21% in 2006.
- The relaunch of chocolate Horlicks in cold format of icy freez, thus delivered a growth of 22% during the year.

- The company has initiated a programme for target acquisitions of health care brands, technologies or business in order to leverage opportunities strategic for the growth of the company.
- As the company's strategy, the top line growth is supported by aggressive advertisement and various sales and marketing initiatives whereas several initiatives were implemented to reduce operating costs in the business.

6.5.5.2 Competitive Advantages

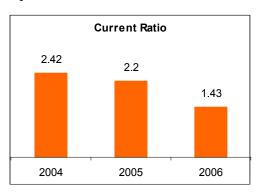
- Horlicks is the leading health food drink in India and enjoys more than 50% of the market share of health food drink market (source: A.C Neilson report on market shares)
- Boost has a market share of 13% countrywide amongst all health food drinks (HFD) while in south India is the biggest region for the category occupying 24% of the market share. (source: A.C Neilson retail audit report)
- Boost was the pioneering brand in this segment to have developed a shrink—sleeved packaging way back in 1999.

6.5.6. Financial Details

6.5.6.1 Revenue

P&L Items (In INR millions)	2004-05	2005-06	2006-07	CAGR%
Sales (net)	9,187.0	1,0890.0	1,2142.0	15.0
Raw Materials Cost	2,161.0	2,502.0	2,750.5	12.8
Raw Materials cost on Sales (%)	23.5	23.0	22.7	-1.9
Employee Cost	1,006.0	1,144.6	1,346.7	15.7
Employees Cost on Sales (%)	11.0	10.5	11.1	0.6
Advertising and Promotion expenses	1,014.0	1,263.0	1,431.0	18.8
Advertising and Promotion expenses as % of				
sales	11.0	11.6	11.8	3.3
Depreciation	414.0	418.0	427.0	1.6
Tax	388.0	589.0	621.0	26.5
PAT	731.0	1,071.0	1,269.3	31.8
EPS (INR)	16.1	24.8	30.2	36.8
Balance Sheet Items	2004	2005	2006	CAGR%
Share capital	454	420	420	-3.81
Fixed Assets (Gross Block + Capital WIP)	3,074	2,838	2,579	-8.40
* There was a buy back of share in 2004				
Source: company website ,Cygnus research				

- The year 2006 was clearly for the brand Horlicks. The 136 year old brand was restaged last year (2005) clocked an impressive growth of 12.8% mainly attributable to intense market research and product innovation.
- The company's current ratio is declining thus showing a positive trend of managing the day to day expenses of the companies.
- The advertising expenses are on rise as compared to last three years which is nearly 11.8% of the total income utilization seeking the strategy of aggressive advertising and marketing promoting the products.



6.5.7. Outlook

- The company is planning targeted acquisition of nutritional brands as the country has huge potential.
- Nutraceuticals was the key focus in 2007. Innovative marketing promotion needs
 were planned to be undertaken to set up vending machines for horlicks and boost
 at schools offices and hospitals inorder to reach customer directly.
- The company has plans to introduce brands from their current global portfolio and add variations to current Indian portfolio so as to expand the presence in the country. They could be Lucozade, a health drink sold in the European market and Sensodyne, a toothpaste for sensitive teeth in the nutritional and OTC segment.
- The company launches protein supplement "ActiBase" under the nutrition category which is an idel blend of soy protein isolate and whey milk protein.

6.6 Himalaya Herbal Healthcare

6.6.1. Company Background

Year incorporated: 1930	Corporate structure: Pvt Co.

Industry Segments				
Pharmaceuticals Ayurvedic Health Care supplements				
	✓	✓		
Consumer care	OTC	Others		

Company overview

- The company was founded by Mr M Manal in 1930 thus highlighting ayurvedic medicines.
- The company has focused on developing safe, natural and innovative remedies.
- Starting up its operations in Dehradun and spread its wings to Mumbai.
 Later in 1975 the company set up manufacturing facility in Bangalore which has the largest tablet coatings with a capacity of ten million tablets are punched per day.
- Himalaya's products are basically categorized in three categories Pharmaceutical, Personal care and Animal health.
- The personal care has health care, hair care, oral care, skincare and baby care.
- Liv52, a liver formulation is the flagship product of the company.
- At present the company has more than 57 exclusive stores, 125 shop-in-shops and 300000 retail outlets comprising chemists and super stores.
- The revenue of the company in FY'07 was INR 5 billion.

6.6.2. Contact Address

Registered Office Address:

The Himalaya drug company Makali Bangalore

India

Tel: +91 80 2371 4444, 4445 Fax: +91 80 2371 4474

Website--www.himalayahealthcare.com

6.6.3. Management Team

6.6.3.1 Board of Directors

Chairman

Mr. Ravi Prasad is the president and CEO of the Indian operations

6.6.4. Leading brands

• Himalaya products range includes pharmaceuticals, personal care, well being and animal care products. Under pharmaceuticals products range, it markets products for health maintenance, eye, cardiac and skin care, immune booster and cough control, etc. The medicinal range includes 35 drugs under 4 major categories of children's health, men's health, women's health and general health like Liv 52, Bonnison, Himplasa, Menosan, Reosto and Tentex royal, apart from other well known products like Abana, Cystone, Gasex, Geriforte, Rumalaya, Diabecon, Pilex, Mentat, Koflet, Himcolin, Septilin, etc.

6.6.5. Business Strategy & Competitive Advantages

6.6.5.1 Strategies

- The company strategy is to emerge as one stop shop in herbal healthcare.
- In a major restructuring of its pharmaceutical division in order to increase its base in the market has set up three strategic business units (SBU's) Zenith, Zandra and Zindel. This in turn will provide an equal and effective market distribution.
- The herbal major, as part of its aggressive retail expansion plan, had tied up with several leading retail chains in the country and abroad.

- Its partners include Big Bazaar, Food World Supermarkets, Spencers, Nilgiris, MKRetails, Shoprite, Giant, D Mart, Ebony, Vishal Mega Mart, Salasaar Bazaar, Lifestyle and Big Shopper.
- The pharmaceutical retail chains that the company has tied up with include Pill & Powder, Apollo Pharmacies, Medicine Shoppe, CRS Health, Medisource, Health & GLow, Guardian Lifecare and 98.4.
- The company has entered in to strategic alliances with the Wild oats, Whole
 foods market and Vitamin Shoppe three natural and organic retail food chains
 with extensive presence in US market to increase accessability and visibility of
 the products in the international market.
- Himalaya launched its forest honey brand (which it aims to target 10 per cent of the INR 450 million -- market (5,000 tonnes)) in the 2003. The major playersn(competitors) were Dabur, Charak, Zandu and Khadi Gramodyog besides unorganised players in the national market.

6.6.5.2 Competitive Advantages

- The company is the First ayurvedic facility to get the 'Good Manufacturing Practices (GMP)' certificate in India in 2001.
- It assures that its pharmaceutical products are designed and developed through good manufacturing practices (GMP), Good Clinical Practices (GCP) and Good Laboratory Practices (GLP).
- Its manufacturing facility has been awarded the ISO 9001- 2000 certificate.
- It is the only company, whose product Liv.52 is registered as a 'pharmaceutical specialty' in Switzerland.

6.6.6. Outlook

- The company plans to expand its presence in the Far East and then move into the markets of China and Japan.
- The company is eyeing contract farming in a big way in southern India so as to
 associate with small and marginal farmers across southern states including Tamil
 Nadu, Andhra Pradesh and Karnataka for sourcing the herbs, the core ingredients
 in herbal drugs.

6.7 Ranbaxy Laboratories Ltd

6.7.1. Company Background

Year incorporated: 1961	Corporate structure: Pub ltd co.

Industry Segments				
Pharmaceuticals	Ayurvedic Health Care			
		supplements		
✓		✓		
Consumer care	OTC	Others		
√	✓			

Company overview

- Ranbaxy Laboratories Limited, headquartered in India, is an integrated, research based, international pharmaceutical company, producing a wide range of quality, affordable generic medicines, trusted by healthcare professionals and patients across geographies
- The Company is ranked amongst the top ten global generic companies and has a presence in 23 of the top 25 pharma markets of the world.
- The Company with a global footprint in 49 countries, worldclass manufacturing facilities in 11 and a diverse product portfolio.
- Ranbaxy Global Consumer Healthcare (RGCH) was established in October 2002 with an objective to promote OTC healthcare brands to consumers.
- The major brands from RGCH include Volini (pain relieving Gel),
 Chericof (Cough Syrup) & Pepfiz (Digestive) revital (nutrition supplement)

6.7.2. Contact Address

Registered Office Address:

Plot 90 Sector 32 Gurgaon 122001, India

India

Tel: 91 124 5135000 Fax: 91 124 5106490 Web: www.ranbaxy.com/

6.7.3. Management Team

6.7.3.1 Board of Directors

Mr. Malvinder Mohan Singh

Mr. Malvinder is the CEO & MD of Ranbaxy Laboratories Ltd. (Ranbaxy).

Dr. Brian W. Tempest

Chief Mentor & Executive Vice Chairman

Dr. Brian W. Tempest assumed the position as Chief Mentor and Executive Vice Chairman of the Board in 2006.

Mr. Atul Sobti

Chief Operating Officer

Mr Atul Sobti is the Chief Operating Officer (COO) at Ranbaxy.

Mr. Ramesh L. Adige

Executive Director, Corporate Affairs & Global Corporate Communications

Mr. Vinay. K. Kaul

Graduated in 1964 (B.Sc. Hons, Physics) from Ramjas College, University of Delhi, Mr.

V.K Kaul joined the Institute of Chartered Accountants of India F.C.A.

Mr. Shivinder Mohan Singh

He is the Director, Ranbaxy Laboratories Limited. He is one of the principal promoters of Fortis Healthcare & SRL Ranbaxy.

Dr. P. S. Joshi

An M.R.C.P from the Royal College of Physicians, United Kingdom, Dr. P.S. Joshi is well known for the pioneering work he has been doing in the field of Cardiology.

6.7.4. Leading brands

Nutritionals

Ranferon / Fenules (Iron supplement), Revital and Riconia (Micronutrients) are the Company's flagship brands in this category. The company launched the Global Consumer Healthcare in order to capitalise on the immense opportunity offered by the Over-The-Counter segment. In the first phase, Revital, Pepfiz, Gesdyp and Garlic Pearls were brought under the new business to be promoted and marketed as OTC brands. The flagship nutritional supplements are

REVITAL SOFTGELS

REVITAL LIQUID

Ginseng, vitamins & minerals

VMS-Vitamins, Minerals & Supplements

6.7.5. Business Strategy & Competitive Advantages

6.7.5.1 Strategies

- The Company has successfully pursued its inorganic growth strategy and concluded over 15 acquisitions since 2004, including the latest 9 acquisitions valued at USD 450 m (4 in Europe, 1 in the US, 3 in India and 1 in South Africa).
- The company acquired a 14.9% stake in the equity capital of Krebs Biochemical Industries Limited for a total consideration of INR 89 million. This strategic move provides the Company with access to low cost manufacturing of fermentationbased products.
- The company enters the Chyawanprash market launching its sugar-free product under the Brand name 'Chyawan Active'. The product marketed by Ranbaxy's Global Consumer Healthcare division, will be initially introduced in North India (Delhi, UP, Punjab and Bihar) and later in other parts of the country.
- In order to capitalize the immense opportunity in the Nutritional and OTC sector the company launched the consumer health care segment.
- With its product innovation strategy the company subsequently in 2004, launched
 its first herbal range of products through New Age Herbals (NAH), with products
 offering remedies in categories of Cough & Cold (Olesan Oil & Cough Syrups)

- and Appetite Stimulant (Eat Ease) in order to enter the market and widen its presence.
- The company pursued a differentiated sales & distribution Strategy of engaging,
 FMCG distributors for its products, and a first of its kind.
- In order to promote its consumer care products the company has chosen a unique Business Communication platform 'The Rainbow Coalition' which is an integrated communication program targeted at doctors at one end and consumers at the other.

6.7.5.2 Competitive advantages

- Company views its R&D capabilities as a vital component of its business strategy
 that will provide the company with a sustainable, long-term competitive
 advantage.
- The distribution infrastructure of company is a unique and first of its kind continues to grow with about 600 Distributors and Distributor Sales Representatives (DSRs) representing the company in the Indian market.

6.7.6. Financial Details

6.7.6.1 Revenue

P&L Items (In INR millions)	2005	2006	2007	CAGR %
Net Sales	34,058.1	39,254.1	40,342.4	8.84
Other Income	2,058.5	795.7	3,413.5	28.77
Total Income	36,116.6	40,049.8	43,755.9	10.07
Expenditure	33,086.7	33,659.6	33,829.1	1.12
Operating profit	3,029.9	6,390.2	9,926.8	81.00
Interest	263.5	581	915.3	86.38
Gross Profit	2,766.4	5,809.2	9,011.5	80.48
Depreciation	1,012.5	1,117.6	1,190.3	8.43
Profit before tax	1,753.9	4,691.6	7,821.2	111.17
Tax	69.3	601.1	1,591.3	379.19
Profit After tax	1,823.2	4,090.5	6,229.9	84.85
Net profit	2,314.2	3,864.5	6,229.9	64.07
Equity capital	1,862.2	1,863.4	1,865.4	0.09
Forex earnings/Exports	23,186.9	27,041.1	NA	
EPS(INR)	6.22	10.37	16.7	63.91
Source: company website ,Cygnus research				

FINANCIAL PERFOMANCE

- Global Consumer Healthcare registered a top line (USD 37 m) 32% growth over the corresponding previous period. Revital, the Company's key brand in the segment continued to perform well having increased its market share from 77% to 84%.
- Revital is currently ranked at No 20 per MAT Nov 07 versus No 35 in the same period last year. The OTC business has recorded a healthy growth of 27% over last year (ORG SSA Mat Nov '07).
- The Volini brand, which was shifted in the early part of the year to the GCHC business, is beginning to show encouraging results post the initiation of the television & media promotion campaign started in Q3 2007 year.

6.7.7. Outlook

- Organic and inorganic growth is planned through strategic alliances and/or acquisitions in the large and exciting OTC and Herbal markets. These expansions will serve the consumer and enhance value for its stakeholders
- In its first phase of geographical expansion, global consumer healthcare segment continues to focus on 'growth countries' which include Russia, Ukraine, Romania, Vietnam, Myanmar and Malaysia. The next stage of expansion is planned in Central and East European countries.

6.8 Zandu Pharmaceuticals

6.81. Company Background

Year incorporated: October 1919

Number of employees: 2000

Corporate structure: ltd co.

Industry Segments				
Pharmaceuticals	ceuticals Ayurvedic Health Care supplements			
✓	✓			
Consumer care	OTC	Others		
✓				

Company overview

- Zandu Pharmaceutical Works (Zandu) is a manufacturer of OYC ayurvedic healthcare products which include rheumatology, gynecology and CNS (Central nervous system) along with chemicals and cosmetics.
- Company's products are available in the US, Europe, Asian and African countries.
- The company is headquartered in Mumbai, India.
- Zandu produces a range of over 300 health promoting products from as many as 200 medicinal plants and their extracts at their up to date plants all across the country.
- Apart from ayurvedic products, it has ventured in to cosmetics and chemcials manufacturing.

6.8.2. Contact Address

Registered Office Address:

Zandu Pharmaceutical Works Ltd 70, Gokhale Road (South) Dadar

Mumbai 400 025

INDIA

Tel: 0263885 430 7021 Fax: 0263885 437 5491

http://www.zanduayurveda.com/

6.8.3. Management Team

6.8.3.1 Board of Directors

Chairman

Y P Trivedi

Mr. Y. P. Trivedi is the former President of Indian Merchants Chamber, The Chamber of Income Tax Consultants, Indo-African Chamber of Commerce.

Managing Director Girish G Parikh Director P P Vora K Natarajan S S Handa A V Shah Executive Director

6.8.4. Leading brands

D M Parikh

It produces more than 300 ayurvedic products like Alpitone, Amalio, Brento, Zandu Balm, Chandraprabvati, Chyavanprash, Drakshavsav, Gulbahar, Kesar-Jivan, Rhumayog tablets, Satavarex granules, Sitopaladi churna, Trishun tablets and rub, Pancharishta, etc.

6.8.5. Business Strategy & Competitive Advantages

6.8.5.1 Strategies

- The company took a strategic decision in September 2006, to make Zandu
 Chemicals Limited (ZCL), a subsidiary of the Company so that the integration of
 activities and nurturing will bring the operational synergies as well as financial
 strategies.
- In the nutra ceuticlas division the company has completed new packaging of Chyavanprash and Kesari Jivan during the year in order to retain its market position.

6.8.6. Financial Details

6.8.6.1 Revenue

P&L Items (In INR millions)	2004-05	2005-06	2006-07	CAGR%
Sales (net)	1,004.91	1,142.41	1,289.05	13.26
Raw Materials Cost	35.61	40.05	51.01	19.69
Raw Materials cost on Sales (%)	3.54	3.51	3.96	5.67
Employee Cost	11.44	11.90	13.04	6.76
Employees Cost on Sales (%)	1.14	1.04	1.01	-5.73
Selling & Administration Cost	32.47	35.37	37.01	6.76
Selling & Administration Cost on Sales (%)	3.23	3.10	2.87	-5.74
PBDIT	142.77	186.05	207.74	20.63
Depreciation	3.02	3.47	3.10	1.32
Interest & Financial Charges	32.47	35.37	37.01	6.76
Tax	37.38	50.01	61.95	28.74
PAT	87.32	122.99	145.96	29.29
EPS (INR)	216.58	203.36	181.01	-8.58
Balance Sheet Items	2004-05	2005-06	2006-07	CAGR%
Share capital	6.05	6.05	8.06	15.42
Fixed Assets (Gross Block + Capital WIP)	231.13	222.38	197.63	-7.53
Total Debt	9.41	3.95	1.96	-54.36
Net Working Capital	24.10	27.43	26.17	4.21
Source: company website ,Cygnus research				

6.8.7. Outlook

- The present environment in the nutracutical industry offers abundant opportunities, considering the brand name of Zandu backed with financial soundness, the Company is embarking upon the growth oriented outlook in the coming year.
- The company is exploring the possibility of entering into Personal Hygiene Care Products and streamlining the distribution network.
- The company has planned to spend effectively on advertisement and sales promotion so as to improve its bottomline in the coming year.

6.9 Zydus Cadila Health Care

6.9.1. Company Background

Year incorporated: 1952

Number of employees: 8,000

Corporate structure: Ltd co.

Industry Segments			
Pharmaceuticals	Ayurvedic	Health Care supplements	
✓			
Consumer care	OTC	Others	
√			

Company overview

- Zydus Cadila is a global healthcare provider and one of the top five pharma companies in India.
- The company was founded by Late Mr. Ramanbhai B. Patel in 1952 and went on to become the second largest pharma company in the early 1990's.
- In 1995, the group restructured its operations and now operates as Cadila Healthcare Ltd., under the aegis of the Zydus group.
- The group has been listed as one of the 'Best under a Billion' company from amongst 200 companies in Asia by Forbes.
- Consumer Products Division (CPD) This Division is a pioneer, offering healthier dietary options to the consumers. The product range comprises Sugar Free Gold– India's No.1 sweetener with a market share of over 70%, Sugar Free Natura– a zero calorie sucralose based sugar substitute, Sugar Free D'lite– a low calorie healthy drink and Nutralite– a premium cholesterol-free table spread.

6.9.2. Contact Address

Registered Office Address:

Cadila Healthcare Ltd Zydus Tower, Satellite Cross Roads, Ahmedabad – 380015 Gujarat, INDIA

Tel: +91-79-26868100 Fax: +91-79-26862365

Website-- www.zyduscadila.com

6.9.3. Management Team

6.9.3.1 Board of Directors

Chairman & M.D.

Mr. Pankaj R. Patel aged 53 years is the Chairman and Managing Director of the company. He is the promoter and founder and has experience of 34 years in pharma industry.

Directors

Mr. Bilpodiwala is a director of the Company since 2003. He is member of the Institute of Chartered Accountants of India and was the senior partner of M/s. Sharp & Tannan, Chartered Accountants.

Mr. Dhanrajgir was the Managing Director of Glaxo India Limited and retired as an Executive Vice Chairman in August 1994.

Mr. Apurva S. Diwanji is an MA from Cambridge University. He is an advocate and solicitor, law society, London, U.K.

Mr. Mukesh Patel, an eminent expert in Direct Taxes, is practicing as an Advocate and Tax Consultant since 1977

Mr. Pranlal Bhogilal, aged 69 years is the chairman of the Das Group. The Das Group is a 100 year group with interest in starches, textiles, engineering, real estate, agriculture and dairying.

Mr. Sharvil P. Patel is a graduate in chemicals and pharmaceutical science (CPS) from the University of Sunderland, U.K and has more than eight years experience in pharmaceutical business.

6.9.4. Leading brands

Health and wellness have been identified as the emerging areas in consumer healthcare. The Consumer Products Division is focused on empowering individuals who wish to adopt healthy eating habits and lifestyles. The Consumer Products Division is a pioneer, offering healthier dietary options to the consumers. The product range comprises Sugar Free Gold– India's No.1 sweetener with a market share of over 70%, Sugar Free Natura– a zero calorie sucralose based sugar substitute, Sugar Free D'lite– a low calorie healthy drink and Nutralite– a premium cholesterol-free table spread.

6.9.5. Business Strategy & Competitive Advantages

6.9.5.1 Strategies

- The company's strategy initially was that the product was launched as healthy sugar alternative but later Sugar Free Natura (a powder form) was launched aimed at penetrating the entire sugar consumption market. As it is a cooking medium the target audience is a homemaker or a woman thus targeting focused market.
- The company's strategy is to focus the domestic market with the consumer division registering a high growth in last three years and with continued new product introductions. The company launched 39 new products in FY 06-07, of which 8 were 1st in India.
- The company in order to keep its market leader ship in this division has made acquisition, with revamped the brand Nutralite, with change in packs, packing style, special promotional campaign and shift of focus from bulk to retail segment, which yielded result in the very first year, and brand recorded sales of over INR 400 mn with 38% growth and positive bottomline.
- Recent addition of a special field force to tap growth potential of rural market, considered to be the next growth driver for the business has showed encouraging results, and has prompted to further expand field force in rural areas.
- In order to remain dominant in the market in this division the company made acquisition of the company Carnation Nutra-Analogue Foods Ltd., and added the product *Nutralite*, to the existing portfolio. During the year (2006-07) the

company revamped and repositioned this brand in the market. With a complete change in the packs and packing style and special promotional campaign, the focus shifted from bulk to retail segment. The company's strategy has started yielding results in the very first year, and the brand recorded sales of INR 427 m, up 38% over last year.

6.9.5.2 Competitive Advantages

- In the consumer division of the company, due to the brand image and standing in the market the company after the acquisition of the business of Carnation reported net profit of INR 39 m, in spite of heavy investments in terms of advertisements and promotions.
- Being the leader in the market the Sugar Free group of products of the company grew by 25%, and crossed INR 500 m mark in 2006-07 thus marking its presence in the market.

6.9.6. Financial Details

6.9.6.1 Revenue

Description	2005-06	2006-07	Growth %
Net Sales(INR m)	12,460	14,137	13.46
Other Income	756	1,004	32.80
Total Income	13,216	15,141	14.57
Expenditure	10,396	11,979	15.22
Operating profit	2,820	3,162	12.13
Interest	205	176	-14.15
Gross Profit	2,615	2,986	14.19
Depreciation	616	667	8.28
Profit before tax	1,999	2,319	16.01
Tax	239	272	13.81
Profit After tax	1,760	2,047	16.31
Net profit	1,649	2,047	24.14
Equity capital	314	628	100.00
Reserves	7,049	8,195	16.26
EPS(INR)	26.26	16.3	-37.93
Source: company website ,Cygnus research			

FINANCIAL PERFOMANCE

- During the year 2006-07, Sugar Free grew by 25%, and crossed mark of INR500 m and registered robust performance with sales of INR 1,219 m, up 89% while Everyuth range of cosmetic products grew by 17%.
- With the acquisition of Carnation last year, the company added one more product Nutralite, to the existing portfolio. The INR 600m margarine category is currently dominated by the Nutralite brand.

6.9.7. Outlook

- Nutraceuticals products are not patent driven and, hence, companies find it easy to launch products. Also, the only cost involved would be that of brand building.
- The lifestyle of people is changing and there is a growing emphasis towards prevention rather than cure. With growing awareness, this category is set to grow in future.
- The Consumer Products Division of Zydus Cadila aims to promote 'healthy living' by anticipating the emerging and day-to-day needs in dietetic / health foods so as to cater to the focused market.

6.10 Amway India

6.10.1. Company Background

Year incorporated: 1994 Corporate structure: Direct selling company

Industry Segments			
Pharmaceuticals	Ayurvedic	Health Care supplements	
		✓	
Consumer care	OTC	Others	
✓	✓		

Company overview

- Amway India is the country's leading direct selling FMCG-company which manufactures and sells world-class consumer products
- Amway India is a wholly owned subsidiary of USD 6.3 billion Amway
 Corporation, Ada, Michigan, USA and is one of the largest Direct Selling
 companies in the world. It has a presence in 88 countries & territories.
- The Indian subsidiary came into existence in the year 1994, though it started its commercial operations in 1998.
- Starting with a modest six products in 1998 today it offers over 80 products in four categories. They are Personal care category, Home Care category, Nutrition & Wellness category and Cosmetics category.
- The company recorded a turnover of INR 7.38 billion during January'06 December'06 and 50 percent of its sales come from the nutrition segment.
- Amway India has 400 full time employees and has generated indirect employment for 1,650 persons at all the contract manufacturer locations.
- Almost all Amway India products are manufactured in the country through
 5 third party contract manufacturers.

6.10.2. Contact Address

Amway India Enterprises A-35, Sector-16 Noida (U.P.)

Tel.: +91-120-3096500 Fax: +91-120-3096552

Wesite--www.amwayindia.com

6.10.3. Management Team

- Doug DeVos is President of Amway and Steve Van Andel is the chairman of Amway Corporation. Doug DeVos is a member of the U.S. Direct Selling Association Board of Directors. Former Alticor President Dick DeVos is current Chairman of the World Federation of Direct Selling Associations (WFDSA).
- Sanker Parmeswaran, Director Corporate Communications and Legal, Amway India Enterprise and Chairman, Indian Direct Selling Association (IDSA)

6.10.4. Leading brands

- At present, Amway India offers over 80 products in four categories. They are Personal care category, Home Care category, Nutrition & Wellness category and Cosmetics category.
- The nutrilite products support every lifestyle and life stage, and are divided into three categories – nutrilite foundation, nutrilite Essentials & nutrilite lifestyle specialty Products.
- Presently, nutrilite is the world's leading vitamins and minerals brand, and is the only global brand that grows, harvests and processes plants in company's own organically certified farms.
- Various nutrilite products are given in the table.

Products	Category
Troducts	Caregory

Double X/Triple X	Multivitamin/Multimineral /containing	
	antioxidant/Supplement	
Omega Product Line	Plant-derived alpha-linolenic acids (ALA) from	
	flaxseed	
Concentrated Fruits and Vegetables	Phytonutrients and antioxidants	
Protein Powder/Nutri-Protein	Protein supplement	
Calcium Product Line	Mineral supplement	
Bio C Plus	antioxidant	
Fruit and Vegetable Fiber	fiber	
Glucosamine HCl	Collagen fiber	
Coenzyme Q10 Complex	Multivitamin supplement	
Carb Blocker/Calorie Just/Calow/CB Plus	Carbohydrate supplement	
Source: company website ,Cygnus research		

6.10.5. Business Strategy

6.10.5.1 Strategies

- The company is repositioning its brands as a health supplements in the market.
- The company is steadily increasing its product line and variants in order to keep up the market demands so that its flagship product nutrilite is not penetrated just in metros but also in semi urban areas.
- The company's strategy is to enlarge its distributors circle with newer sales force thus maintaining its market position.
- The company is focusing on doctors and medical practitioners in order to promote its health products in the market.

6.10.6. Outlook

- The company is in the process of focusing on as many as 5,000 doctors and health practitioners to promote its health supplements in the coming future.
- The company is heavily expanding its product line to cater to the new age consumer, as it introduces as many as 10 products every calendar year.
- The company is also venturing into to introduce the products for mass market.
- The company intends to invest INR120-140 million on promotional activities in 2007-08.
- The company has 6-8 products in its product pipeline to be launched in 2007-08.

6.1 Tablets India Limited

6.11.1. Company Background

Year incorporated: 1938	Corporate structure: Ltd co.
Number of employees: 1,120	-

Industry Segments			
Pharmaceuticals	Ayurvedic	Health Care	

Company overview

- Tablet India limited (TIL) is one of the leading manufactures of various types of pharmaceuticals and nutraceuticals formulations.
- In 1938, entered into healthcare industry with an acquisition of a British owned oakely & Bowden company in south India.
- The company's business is operated through five divisions
 - o Domestic health care formulations business
 - o Tile care division
 - o Animal health division
 - OTC Division
 - o Overseas division
- Tablet India ltd has international tie ups with Japanese multinational Roussel Morishita Co. ltd
- Company has agreement with F. Hoffmann La Roche, a Switzerland company for manufacturing and marketing of life saving products in anaesthesiology & Gastroentrology.
- Company has also entered into agreement with TOA Pharmaceutical
 C o. Ltd., Japan for a exclusive probiotic product.

6.11.2. Contact Address

Registered Office Address:

Tablets (India) Limited
"R.A.Building"
72, Marshalls Road, IV Floor,
Chennai 600 008. India

E-Mail: info@tabletsindia.com

Tel: +91 (44) 4205 0000 Fax:+91 (44) 2858 9090

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6.11.3. Management Team

6.11.3.1 Board of Directors

Chairman & M.D: Mr. R.K. Jhaver

6.11.4. Leading brands

- Tablet India limited focuses on manufacturing of various types pharmaceuticals and nutraceuticals formulations. It includes wide therapeutic range of products are nutritional supplements, haematinics, hepatoprotectives, novel antipyretic, a unique Gastrointestinal Lavage preparation, Anti-Ulcerant, Osteoporotic Formula, and Respiratory Medicine.
- ➤ It includes wide range of products in nutraceuitcals.

Combination	Brand Name
Oral Amino acid Multivitamin/Mineral Formulations	Astymin-M Fort
	 Astymin-c Drops
	 Astymin Liquid
	 Astyvit
	 Astymin Forte
	 Astymin-z Forte
Parenteral amino acid Formulations	Astymin-3(20ml)
	■ Astymin-3 (200ml)
	Astymin-SN
Haematinices containing Iron, Vitamins & Amino acids	Astyfer-Cap
	Astyfer-Z Cap
	 Astyfer Liquid
	 Astyfer-Z liquid
Calcium preparations	■ Aminocal
Multivitamin injections	■ Tilvit
Anti-oxidants	 Antoxyl forte (glutathione based novel anti-oxidant)

➤ It also includes OTC products

Combination	Brand name
Oral electrolytes	 Dextrolyte
Peripheral vasodilaters	Perivalan
Anti-cholin esterase agents	■ Tilstigmin tab/inj
Amoebicides	 Tilemetin inj

Source: company website ,Cygnus research

They have also entered into Probiotics for woman health which is booming market.

6.11.5. Business Strategy & Competitive Advantages

6.11.5.1 Strategy

- TIL has wide network in India for distribution of products, C&F alone distributes to 1000 stockiest who in turn covers 1, 50,000 retailers.
- They operate business with five divisions. In domestic market, they market all branded formulations through well trained field force and meet all specialties doctors. Brand recall is very high and more prescription are generated.
- TIL care division mainly focusing on specialties hospital injectables and also plan to introduce critical care injectables which has high demand in the market.

6.11.5.2 Competitive advantage

TIL has first launched a unique product with brand name Ecoflora in the area
of probiotics concept for women's health. Product has been appreciated by
India medical community and which has positive opinion for the use of
probiotics.

6.11.6. Outlook

- The company having wide range of products in nutraceuitcals is likely to grow as brand recall drives the company's products presence in the market.
- The company is launching unique products called Ecoflora (probiotics) targeting women is likely to drive the top line of the company in this segment.

6.12 Raptakos, Brett & Co.Ltd

6.12.1. Company Background

Year incorporated: 1930 Corporate structure: Ltd co.

Company overview

- Raptakos, Brett & Co.Ltd., was founded in India in 1930 by Mr.A.Raptakos and Mr.W.H.Brett.
- The company has a wide range of nutraceutical products ranging from specialized infant foods for low birth and weight and lactose intolerance infants foods for growing children, diabetics, cardiac patients, pregnant and lactating women, and the old and critically ill.
- The company has an extensive distribution network comprising 24 branches spread all over India. Over 1000 field personnel serve the medical professionals through out the country.
- The company has established its presence in international markets in Asia, Africa, South America and Europe through its offices in Vietnam, Philippines, Kenya, Middle East, South Africa and the UK.
- Pioneers in nutraceuticals
- The first company in India to introduce an innovative and unique drug delivery system called the Diffusion Rate Controlling Membrane.

6.12.2. Contact Address

Registered Off:

M/s Raptakos Brett & Co. Ltd. 253,Dr Annie Besant Road, Worli, Mumbai - 400 030.

Tel: 022 24934251, Fax: 022 24950341

E-mail: contact@raptakos.com website--www.raptakos.com

6.12.3. Products

The company has a wide range of nutraceutical products ranging from specialized infant foods for low birth and weight and lactose intolerance infants foods for growing children, diabetics, cardiac patients, pregnant and lactating women, and the old and critically ill. The products are given below with category of people consuming them.

Products	Category	
CERELYTE (Rice based ORS, Zinc)	General	
EASIFUD (rice based weaning food for infants)	Infants	
IGOL(fiber)	General	
IGOL Pearls(fiber)	General	
IGOL-D(fiber)	For diabetic patients	
IMMUNOSTRUM (nutritional supplement immunity enhancement)	General	
ISOFLAV CAL TABLETS (Management of menopausal symptoms)	Women(aged)	
ISOFLAV CR CAPSULES (Dietary supplement for post-menopausal	Women(mostly middle aged	
women)	group)	
ISOFLAV PLUS (For Smoother Transition from Peri- Menopause to	Women	
Menopause)		
LACTODEX(Infant milk substitute)	Infants	
LACTODEX 3(Nutritionally balanced follow up formula for older infants)	Infants	
NUTRICARD (Soynergestic Nutrition for the heart)	For heart patients	
NUTRIMOM(A Nutritional supplement)	For pregnant women and Lactating mothers	
PRORICH DISKETTE POWDER (protein supplement)	General	
THREPTIN DISKETTES (The anytime-anywhere meal)	General	
TROPHOX (Soybetic Nutrition supplement)	for Diabetic Patients	
VEELAC CLASSIC rice, wheat, apple (Milk-Cereal Based Complimentary	General	
Food)		
ZEROLAC (The sucrose-free, milk protein-free, zero-lactose formula)	Infants with milk allergy	
Source: company website ,Cygnus research		

6.12.4. Outlook

- Being pioneers in nutraceuticals the company is likely to grow in coming years as
 its product has wide range catering to almost all age group, gender and targeting
 specific therapeutic segment.
- Health awareness among consumers is on a rise which in turn is likely to drive the nutraceutical products of the company.

6.13 Sami Labs

6.13.1. Company Background

Year incorporated: 1991

Number of employees: 1,200 approx

Corporate structure: Ltd co.

Industry Segments		
Pharmaceuticals	Ayurvedic	Health Care supplements
	✓	✓
Consumer care	OTC	Others
✓		

Company overview

- Sami Labs Ltd, is a research oriented transnational health science company, which is a leading producer of nutraceuticals, cosmoceuticals, standardised herbal extracts, fine chemicals, specialty chemicals and probiotics.
- Sami Labs Ltd also offers a state-of-the-art research facility for contract research.
- Sami Labs has a modern R&D center supported by a full fledged
 Pilot plant, production and testing facilities.
- The global revenue of the company stood at USD 110 million (for 2005), with an employee strength of 50 people in USA and Japan, more than 1000 in India and over 100 scientists worldwide. Sami Labs is into farming also covering 40,000 acres of land in India.

6.13.2. Contact Address

Registered Office Address:

Sami Labs Limited, 19/1 & 19/2, I Main, II Phase, Peenya Industrial Area, Bangalore - 560 058. Karnataka, INDIA.

Ph: 91-80 - 28397973-75, 78

Fax: 91- 80 -28373035 E-Mail: mail@samilabs.com Website: www.samilabs.com

6.13.3. Management Team

Chairman

Dr. R K Bammi obtained his MS and Ph.D from the University of California has nearly 35 years of experience in Pharmaceutical, R&D and manufacturing management.

Todd Norton Director

He has played a pivotal role in the development of Sabinsa Corporation since 1994 and has been instrumental in the phenomenal growth of the company.

Dr. M D Nair

He holds a Ph.D. from USA in Organic Chemistry. He has worked with CIBA - GEIGY pharmaceutical research group in Switzerland and Mumbai.

Humayun Dhanrajgir

He was the Executive Vice Chairman and Managing Director of Glaxo India He was also the President of OPPI (Organisation of Pharmaceutical Producers of India) for 2 years in 1990-92

Ms Sami Faazal

Ms. Sami Faazal is the daughter of Dr Muhammed Majeed, Chairman & Managing Director

She had her graduation in Business Management from USA. She is involved with the Commercial and Administrative activities of the company.

P N Venugopalan

He has an impressive working experience of 40 years in the field.

6.13.4. Leading Products

- Sami has a portfolio of 200-odd nutraceutical ingredients and products, of which a
 handful are available in the country. Some of Sami's clients are Avon, Estee
 Lauder, L'Oreal, Godrej and HLL.
- Sami labs products range include Standardized extracts, natural cosmoceuticals, probiotics and enzymes, spice extracts, minerals, fine chemicals, phyto-chemicals and oils.
- The standardized extracts products group has more than 95 products including Adhatoda vasica extract, Amla extract, Ashwagandha extract.
- The company manufactures about 26 natural cosmoceuticals products, which includes Alpha Lipoic acid, Boswellin, Cococin, etc.
- Sami lab also manufactures Lactospore probiotics and Dizizyme enzyme.
- Under the product group of spice extract, the company has 29 products and some are Bioperine, capsaicin, Citrin and Curcumin, etc.
- It manufactures 26 mineral products like Calcium Ascorbate, copper lysinate, magnesium citrate, etc. 21 fine chemical and phyto chemical products that includes
- 1,2 Hexanediol, Berberine Sulfate, Di-Indolyl-Methane are also manufactured here.
- The company manufactures about 9 oils mostly of plant origin, including Coleus forskohlii oil, Coriander oil, Flaxseed oil, etc.

6.13.5. Business Strategy & Competitive Advantages

6.13.5.1 Strategies

- To cater to the expanding global market, the company has its presence and strategic alliances in USA, Europe, Japan, Australia, Middle East and South Africa.
- The company has initiated clinical trials on some of its existing products, to tap a part of the nutraceutical market in Japan, the US and Europe.

- The company is in the process of building a worldwide core marketing team for introducing its branded products through multi-level marketing (MLM) model and has lined up many nutraceutical and cosmoceutical products under the brand 'Johar'.
- Herbal extracts and nutraceuticals export major Sami Labs Ltd has formed its first
 joint venture through a Malaysian foray to cultivate and produce new herbal
 ingredients since Malaysia has several unique and untapped medicinal plants with
 a large potential as sources of nutraceuticals and cosmoceuticals (herbs with
 nutritive and cosmetic value).
- Sabinsa Group, a wholly-owned subsidiary of Sami Labs Ltd., India, established
 an exclusive marketing partnership with Goldschmidt Personal Care, a whollyowned subsidiary of Degussa GmbH, in which Goldschmidt will distribute select
 specialized, standardized botanical extracts from Sabinsa, all specifically
 developed for cosmoceutical use, to the personal care industry worldwide.
- The company's turnover for the year 2005-06 was INR 4.9billion.
- The company comprises of wide portfolio of 200-odd nutraceutical ingredients and products.
- The company has focused on niche segments of traditional plants which do not occur commonly like pysllium and coleusforskohlii.
- The clintele includes multinational and Indian FMCG companies like Avon, Estee Lauder, L'Oreal, Godrej and HLL.

6.13.5.2 Competitive Advantages

- The company has 22 US patents, 4 European patents, and one patent in UK and Australia and three from other parts.
- Product merit award by Nutrition Business Journal for Selenomethionine and ForsLean (February-2006) for Sabinsa Corporation.
- The company has developed good documentation for safety and efficacy and for conducting its clinical trials in the U.S. on American population that was crucial in establishing its bonafides and conducting multiphase and multi location clinical trials, has a distinct marketing edge.

6.13.6. Outlook

- The company plans to introduce 20-25 new drug formulations every year for the next five years as it has focused in the niche market segment of pysllium and coleus forskohlii.
- The company plans to strengthen its marketing muscle abroad in order to strengthen its market presence.
- To increase its income from India the company plans to launch its cosmoceuticals under the brand name 'Johara' within a year.
- The Indian nutraceuticals scene is an untapped goldmine and the company is
 eyeing the huge gap in the market mainly for anti-oxidants, preventive and
 supportive therapeutics.

6.14 British Biologicals

6.14.1. Company Background

Year incorporated: 1988

Number of employees: 500

Corporate structure: Ltd co.

Industry Segments		
Pharmaceuticals	Ayurvedic	Health Care supplements
✓		✓
Consumer care	OTC	Others
✓	✓	

Company overview

- British Biologicals as an innovative and pioneering nutraceutical company found in 1988.
- British Biologicals is in the forefront offering Nutritional supplement in nutritionally beneficial and condition based specialties like General Nutrition, Diabetes, Pregnancy and Lactation, Respiratory Disorders, Menopause and Hepatic dysfunctions.
- This manufacturing facility conforms to the US FDA and WHO GMP standards, and has a built up area of 11,664 sq.mtrs and a capacity to produce 0.25 million bottles per day
- British Biologicals has two manufacturing facilities in Karnataka. The
 first unit was commissioned in the year 1988. The second State-of-theart manufacturing facility emerged in the year 2001 to meet the
 increasing demands in both the domestic and international markets.

6.14.2. Contact Address

Registered Office Address: British Biologicals, 27, Elephant Rock Road, 3rd Block Jayanagar, Bangalore 560011

Tel: +91-80-26635242 / 26637241 /

26548257 / 26534503 Fax: +91-80-26632414

6.14.3. Management Team

6.14.3.1 Board of Directors

Chairman& M.D: V.S REDDY MD

6.14.4. Leading brands

British biologicals are focused into nutraceutical sector which has products in different segments like General health, Women's health, Child health, Diabetes, Respiratory, and Liver.

It consists of following products:

SNO	Therapeutic segment	Brand name	therapeutic Action	
1	General health	B-protein	-Pre& postoperative care	
2	Women's health:	Pro-pl Meno pro	-pregnancy and lactation -menopausal symptoms	
3	Childs health	Kids-pro	- nutritional drink	
4	Diabetes	D-protein	-diabetic and obese patients	
5	Respiratory	Pulmocare	-chronic obstructive pulmonary diseases - Tuberculosis & RTI	
6	Liver	Hepapro	jaundicecirrhosishepatitis	
Source: company website ,Cygnus research				

General health:

B-Protein: It is available in chocolate, mango, pineapple, chocolate with dry fruits. B-protein is mainly used in pre & postoperative care, convalescence, pregnancy, lactation, trauma in burns, radiation therapy, chemotherapy, infection, sepsis & general nutritional support.

Women's health:

PRO-PL: Pro-PL is a dietary support during pregnancy & lactation is available in Cardamom flavor. It is a tailor made formula for pregnant & lactating women with the right blend of essential ingredients to meet the increased energy demand in pregnancy & lactation.

British biologicals launched with reformulation of Pro-Pl with the combination of Docosahexaenoic acid (DHA) and Gamma linolenic acid (GLA), where DHA and GLA are very important in developing baby's brain, vision, heart development, which is scientific combination for the first combination in India. It is available in three different flavors vanilla, chocolate, and cardamom with real flavor.

Meno pro: Meno Pro helps in alleviating menopausal blues, and is available in honey nut crunch flavor. The protein supplement enriched with isoflavones for alleviation of menopausal symptoms, a major irritant in middle-aged women

Child health:

KIDS-PRO: THIS Product is available in three flavors in the market. It is a nutritional drink for children with amino acids, with protein, vitamins & minerals. It's a healthy nutritional formula for all round development of children.

Diabetes:

D-Protein: D-Protein is available in chocolate Columbian Coffee flavors. It is an ideal supplement for dietary management, particularly in diabetics & obese people. Its unique low fat- complex carbohydrate combination helps control blood glucose level.

Respiratory:

Pulmocare: It acts as supportive nutrition in pulmonary care in conditions such as COPD, Tuberculosis & RTI.

Liver:

Hepapro: Hepa Pro is a complete hepatic support preparation to augment liver function and is available in mixed fruit flavor. It has nutrients to reverse pathological liver changes in conditions such as jaundice, cirrhosis & hepatitis.

6.14.5 Business Strategy & Competitive advantages

6.14.5.1 Strategy

- The company has introduced ColRed, a nutraceutical drink in powder form for the reduction and control of cholesterol.
- The company manufactures disease specific nutritional supplements based on the therapeutic uses and targets consumers in the niche segment of the Indian market.
- Currently the company's products are marketed in more than 20 countries.

6.14.5.2 Competitive advantages

- Having a strong sales and marketing network backed by over 400 strong field executives servicing more than 75,000 medical specialists and over 2,00,000 retail outlets through 1,000 odd distribution points the company markets its products.
- The company is stated to be growing at the rate of 30%.
- The company has associations with Institute of Food Technologists, USA;
 Leatherhead Food, UK; American Diabetic Association and the American Heart Foundation.
- It is the only Indian company to export the nutraceutical supplements to the United Kingdom.

6.14.6. Outlook

- The company has a strategic plan to focus nutraceutical products targeting sports and gym fanatics.
- The company is in the process of finalizing agreements in Europe and Russia so as to enter these markets.
- The company also plans to launch its products in the US market.

REGULATIONS

Nutraceuticals, the world over, falls under a grey area. In most developed nations, including the US, one or more categories of ingredients are not permitted to be sold within food law, but in an intermediate category between food and pharmaceutical law or under pharmaceutical law. In Australia, Canada and South Africa, all dietary supplements have been placed in a separate category. A dietary supplement (also known as food supplement) is a preparation intended to supply nutrients, (such as vitamins, minerals, fatty acids or amino acids) that are missing or not consumed in sufficient quantity in a person's diet. Some countries define dietary supplements as foods, whilst in others they are defined as drugs. In the United States, the definition of dietary supplements includes non-medicinal herbal supplements and hormones, such as DHEA, pregnenolone (both steroids) and melatonin. Supplements containing vitamins or dietary minerals are recognised by the Codex Alimentarius Commission (the United Nations' highest authority on food standards) as a category of food.

7.1 USA

The Dietary Supplement Health and Education Act (DSHEA or the Act) of 1994 was enacted by Congress following public debate concerning the importance of dietary supplements in leading a healthy life, the need for consumers to have current and accurate information about supplements, and controversy over the Food and Drug Administration's (FDA) regulatory approach to dietary supplements. This legislation defines dietary supplements, places the responsibility for ensuring their safety on manufacturers, identifies how literature may be used in connection with sales, and specifies types of statements of nutritional support that may be made on labels, specifies certain labeling requirements, and provides for the establishment of regulations for good manufacturing practices. The legislation creates an Office of Dietary Supplements (ODS) in the National Institutes of Health (NIH), with a mandate to coordinate scientific research relating to dietary supplements within NIH and to advise Federal agencies on issues relating to dietary supplements. Under DSHEA act 1994 the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is

marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading. FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising. Domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States is required to register their facility with the FDA. In the United States, a dietary supplement is defined under the Dietary Supplement Health and Education Act of 1994 (DSHEA) as a product that is intended to supplement the diet and bears or contains one or more of the following dietary ingredients:

- 1. a vitamin
- 2 a mineral
- 3. an herb or other botanical (excluding tobacco)
- 4. an amino acid
- 5. a dietary substance for use by people to supplement the diet by increasing the total dietary intake, or
- 6. a concentrate, metabolite, constituent, extract, or combination of any of the above

Furthermore, it must be:

- 1. intended for ingestion in pill, capsule, tablet, powder or liquid form
- 2. not represented for use as a conventional food or as the sole item of a meal or diet
- 3. labeled as a "dietary supplement"

Pursuant to the DSHEA, the Food and Drug Administration regulates dietary supplements as foods, and not as drugs. Unlike pharmaceutical companies, supplement manufacturers are not required to prove the safety or effectiveness of their products; the FDA can take action only after a dietary supplement has been proven harmful.

7.2 European Union

The Food Supplements Directive requires that supplements be demonstrated to be safe, both in quantity and quality. Some vitamins are essential in small quantities but dangerous in large quantities, notably Vitamin A. Consequently, only those supplements that have been proven to be safe may be sold without prescription. In practice, however, there appears to be little risk to supplement users of experiencing adverse side effects due to excessive intakes of micronutrients.

In Europe, it is also an established view that food supplements should not be labeled with drug claims but can bear health claims, although to a degree that differs from one member state to the other.

The Codex Alimentarius Commission, organized by the United Nations in the 1960s, is charged with harmonizing food and supplement rules between all nations of the world. Under Codex rules, even basic vitamins and minerals require a doctor's prescription. The European Union already has adopted Codex-type regulations, regulations that will be in effect across Europe.

7.3 Japan

In Japanese nutraceutical industry, there are two categories of functional foods one is regulated, (known as FOSHU or Tokuho in Japanese) that can claim health benefits, and the other is unregulated or non-FOSHU which can't make any heath claims. The Japanese system is based on a list of approved foods and ingredients that the Japanese Department of Health approves after enough scientific evidence to support health claims. This system was put into place in 1993 in the country. In order for a product to be approved as FOSHU, companies need to go through an application process that takes about one year and are reviewed by local prefecture authorities and the Ministry of Health and Welfare (MHW). The Applications must include scientific documentation demonstrating the medical or nutritional basis for a health claim, the basis for the recommended dose of the functional ingredient, information demonstrating the safety of the ingredient, information on physical and chemical characteristics, relevant test methods, and a compositional analysis.

7.4 India

The food sector in India is governed by a multiplicity of laws under different Ministries. A number of committees, including the Standing Committee of Parliament on Agriculture in its 12th Report submitted in April 2005, have emphasized the need for a single regulatory body and an integrated food law. The Indian Food Safety and Standards Bill 2005 has been signed into law, promising a major impact on the Indian Food Processing Industry. The Food Safety and Standards Act aims to integrate the food safety laws in the country in order to systematically and scientifically develop the food processing industry and paradigm shift from a regulatory regime to self-compliance. As part of the process of consolidation, the Act proposes to repeal eight existing laws related to food safety.

The main objectives of the Act are:

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

The Act aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command. It incorporates the salient provisions of the Prevention of Food Adulteration Act 1954 and is based on international legislations, instrumentalities and Codex Alimentarius Commission.

Highlights of the Act:

• The Food Safety and Standards Act, 2005 consolidates eight laws governing the food sector and establishes the Food Safety and Standards Authority (FSSA) to regulate the sector and other allied committees. The FSSA would consist of a Chairperson and 22 members. The Chairperson would be either an eminent food scientist or a civil servant not below the rank of Secretary. Seven of the members would be ex-officio, not below the post of Joint Secretary, from various ministries. Five members would be appointed by rotation every three years from the states and Union Territories. The Authority would have two representatives each from the food industry and consumer

organizations, three food technologists, and two members from a farmers' organization and one from retail organization. FSSA will be aided by several scientific panels and a Central Advisory Committee to lay down standards for food safety. These standards will include specifications for ingredients, contaminants, pesticide residue, biological hazards, labels and others.

- Everyone in the food sector is required to get a license or a registration that would be issued by local authorities. Temporary stall holders are exempted from the license but need to get their businesses registered with the local municipality or Panchayat.
- The law will be enforced through State Commissioners of Food Safety and local level officials. The Act empowers the FSSA and State Food Safety Authorities to monitor and regulate the food business operators. The Commissioner of Food Safety of each state appoints a Designated Officer (DO), not below the level of Sub- Divisional Officer, for a specific district whose duties include issuing or canceling licenses, prohibiting sale of food articles that violate specified standards, receiving report and samples of food articles from Food Safety Officers and getting them analyzed. The State Commissioner, on the recommendation of the Designated Officer, decides whether a case of violation would be referred to a court of ordinary jurisdiction or to a Special Court.
- The Act provides for a graded penalty structure where the punishment depends on the severity of the violation. Offences such as manufacturing, selling, storing or importing sub-standard or misbranded food could incur a fine. Offences such as manufacturing, distributing, selling or importing unsafe food, which result in injury could incur a prison sentence. The sentence could extend to life imprisonment in case the violation causes death. Petty manufacturers who make their own food, hawkers, vendors or temporary stall holders could be fined up to INR 25 thousand if they violate the specified standards.
- New Judicial process:

In order to judge cases related to breach of specified regulations, the state government has the power to appoint an Adjudicating Officer, not below the rank of Additional District Magistrate. Any person not satisfied by the decision of an Adjudicating Officer has the right to appeal to the Food Safety Appellate Tribunal (or to the State Commissioner until the Tribunal is constituted). The Tribunal enjoys the same powers as

a civil court and decides the penalty in case of non-compliance with the provisions of the Act.

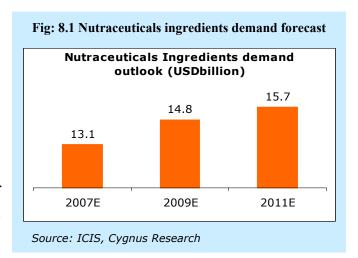
• Food Recall Procedures: Every distributor is required identify any food article to its manufacturer, and every seller to its distributor. Anyone in the sector should be able to initiate recall procedures if he finds that the food sold had violated specified standards.

India has the base of ayurveda, and therefore it is easier for Indians to study nutraceuticals and explain and conceive their clinical efficacy. Ayurvedic and unani medicines are herbo-mineral based. Modern medicine has certain parameters related to drug discovery but these parameters are unreasonable to validate nutraceuticals. The guidelines should, therefore, be similar to regulatory requirements for ayurveda, siddha, unani or homeopathy. The regulatory body may classify the products as purely herbal, which should be endorsed through the PFA act and formulations containing minerals and vitamins through the drug authorities. All the GMP parameters applicable to ayurvedic manufacturing units should be applicable to herbo-mineral formulations and hygiene regulations of PFA act for herbal compositions. Some Indian nutraceutical manufacturers have done their labeling as per the law of US Government. 'This product should not be consumed during pregnancy' is one example very commonly seen on the labels. Ayurvedic products are not supposed to mention any such clause. Therefore, the law for nutraceuticals for the Indian market should also include such considerations. As there is a list of books available in Schedule 1 of Drugs and Cosmetics Act for approval of ayurvedic formulations, government should also make a list of international journals for references of the nutraceuticals.

8. FUTURE OUTLOOK

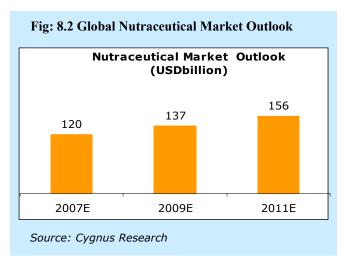
The universal desire to be healthier is driving the nutraceuticals market. The Nutraceutical industry is increasingly being regulated world wide for standardization and product claims. As per Cygnus estimates the global demand for nutraceuticals is likely to

reach USD156billion by 2011 growing at a CAGR of 6.8% for the last five years as figured in the graph. The nutraceuticals ingredients demand is likely to grow to from USD12.4billion in 2006 to USD 15.7billion in 2011 growing at a CAGR of 6.1%. Specifically the demand for herbal and non-herbal extracts is



likely to rise by 6.5 % annually to USD 2.5billion and that of nutrients and minerals by 6.3 %, to USD1.27b and for vitamins the growth will be slower at 4.6 % annually to USD

5.2b in 2015. Soft drinks and dietary products are likely to grow fast than the other segments due to the worldwide awareness and acceptance in the functional food segment. High growth opportunities are likely to be seen in the coming years in soy protein nutrients, the functional food ingredients like lutein, lycopene, omega-3 fatty

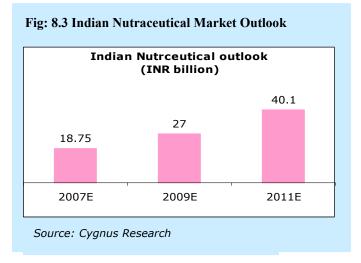


acids, probiotics and sterol esters, the essential minerals calcium and magnesium, the herbal extracts garlic and green tea and the non-herbal extracts chondroitin, glucosamine and coenzyme Q10. The US is set to remain in its position as largest consumer because

while growth in China and India will be related to strong economic growth and the subsequent upgrading and diversification of food, beverage and drug production capabilities.

The domestic market is different as compared to world over; the nutraceuticals are a part of OTC market, where as in India they come under the prescription band as well as OTC

segment. The market size of nutraceuticals as per Cygnus estimates in 2007 was INR 18.7 billion and is likely to reach INR 40.1 billion in the year 2011 growing at a CAGR of 21.23 % as depicted in the figure. The nutraceutical industry, positioned somewhere between the food and pharmaceutical sectors, presents an



interesting investment opportunity, characterized by low regulatory barriers and rapidly rising consumer demand in the domestic market.

Nutraceuticals are destined to play an important role in future therapeutic developments but their success will be governed by control of purity, safety and efficacy without inhibiting innovation. Nutraceuticals will continue to appeal health conscious consumers because they are convenient for today's lifestyle. Some are also genuinely researched and offer novel ingredients that can bring about health benefits quicker than would normally be the case through eating conventionally healthy foods alone. A place for nutraceuticals in clinical practice is emerging, but important pharmaceutical and clinical issues need to be addressed by further research.

ANNEXURE I

Dietary Supplement Health and Education Act of 1994

1. Short Title

This Act may be cited as the "Dietary Supplement Health and Education Act of 1994".

Reference Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

Table of Contents

- Sec. 1. Short title; reference; table of contents.
- Sec. 2. Definitions
- Sec. 3. Safety of Dietary Supplements and Burden of Proof on FDA
- Sec. 4. Safety of dietary supplements and burden of proof on FDA.
- Sec. 5. Dietary supplement claims.
- Sec. 6. Statements of nutritional support.
- Sec. 7. Dietary supplement ingredient labeling and nutrition information labeling.
- Sec. 8. New dietary ingredients.
- Sec. 9. Good manufacturing practices.
- Sec. 10. Conforming amendments.
- Sec. 11. Withdrawal of the regulations and notice.
- Sec. 12. Commission on dietary supplement labels.
- Sec. 13. Office of dietary supplements.

2. Definitions

(a) Definition of Certain Foods as Dietary Supplements. Section 201 (21 U.S.C. 321) is amended by adding at the end the following:
"(ff) The term "dietary supplement" -
(1) Means a product (other than tobacco) intended to supplement the diet that bears of contains one or more of the following dietary ingredients:
(A) a vitamin;
(B) a mineral;
(C) An herb or other botanical;
(D) An amino acid;
(E) A dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) A concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
(2) Means a product that -
(A)(i) Is intended for ingestion in a form described in section 411(c)(1)(B)(i); or
(ii) Complies with section 411(c)(1)(B)(ii);
(B) Is not represented for use as a conventional food or as a sole item of a meal of the diet; and
(C) Is labeled as a dietary supplement; and

(3) Does -

(A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) Not include -

- (i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or
- (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.

- **(b) Exclusion from Definition of Food Additive.** Section 201(s) (21 U.S.C. 321(s)) is amended -
 - (1) By striking "or" at the end of subparagraph (4);
 - (2) By striking the period at the end of subparagraph (5) and inserting "; or"; and

- (3) By adding at the end the following new subparagraph (6) "an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.".
- (c) Form of Ingestion. Section 411(c)(1)(B) (21 U.S.C. 350(c)(1)(B)) is amended-
 - (1) in clause (i), by inserting "powder, softgel, gelcap," after "capsule,"; and
 - (2) In clause (ii), by striking "does not simulate and".

3. Safety of Dietary Supplements and Burden of Proof on FDA

Section 402 (21 U.S.C. 342) is amended by adding at the end the following:

- (f)(1) If it is a dietary supplement or contains a dietary ingredient that -
- (A) Presents a significant or unreasonable risk of illness or injury under -
- (i) Conditions of use recommended or suggested in labeling, or
- (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
- (B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;
- (C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration; or
- (D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

4. Dietary Supplement Claims

Sec. 403B.

- (a) IN GENERAL A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it -
 - (1) is not false or misleading;
 - (2) Does not promote a particular manufacturer or brand of a dietary supplement;
 - (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
 - (4) If displayed in an establishment, is physically separate from the dietary supplements; and
 - (5) Does not have appended to it any information by sticker or any other method.

- **(b) APPLICATION.** Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.
- **(c) BURDEN OF PROOF.** In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.".

5. Statements of Nutritional Support

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end the following:

- (6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if -
 - (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,
 - (B) The manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
 - (C) The statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall

notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made."

6. Dietary Supplement Ingredient Labeling and Nutrition Information Labeling.

- (a) MISBRANDED SUPPLEMENTS. Section 403 (21 U.S.C. 343) is amended by adding at the end the following: "(s) If -
 - (1) It is a dietary supplement; and
 - (2)(A) The label or labeling of the supplement fails to list -
 - (i) The name of each ingredient of the supplement that is described in section 201(ff); and
 - (ii)(I) the quantity of each such ingredient; or
 - (II) With respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;
 - (B) the label or labeling of the dietary supplement fails to identify the product by using the term 'dietary supplement', which term may be modified with the name of such an ingredient;
 - (C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;
 - (D) the supplement -
 - (i) is covered by the specifications of an official compendium;
 - (ii) is represented as conforming to the specifications of an official compendium; and
 - (iii) fails to so conform; or

- (E) the supplement -
- (i) is not covered by the specifications of an official compendium; and
- (ii)(I) fails to have the identity and strength that the supplement is represented to have; or
- (II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.".
- **(b) Supplement Listing on Nutrition Labeling.** Section 403(q)(5)(F) (21 U.S.C. 343(q)(5)(F)) is amended to read as follows:
 - (F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that -
 - (i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;
 - (ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;
 - (iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

- (iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.".
- (c) Percentage Level Claims. Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding after clause (E) the following:
 - (F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.".
 - (d) Vitamins and Minerals. Section 411(b)(2) (21 U.S.C. 350(b)(2)) is amended -
 - (1) by striking "vitamins or minerals" and inserting "dietary supplement ingredients described in section 201(ff)";
 - (2) by striking "(2)(A)" and inserting "(2)"; and
 - (3) by striking subparagraph (B).

(e) Effective Date. Dietary supplements -

- may be labeled after the date of the enactment of this Act in accordance with the amendments made by this section, and
- shall be labeled after December 31, 1996, in accordance with such amendments.

7. New Dietary Ingredients

Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

NEW DIETARY INGREDIENTS

- **SEC. 413.** (a) **IN GENERAL.-** A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:
 - (1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.
 - (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

(b) PETITION. - Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, United States Code, the decision of the Secretary shall be considered final agency action.

(c) DEFINITION. - For purposes of this section, the term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.".

8. Good Manufacturing Practices.

Section 402 (21 U.S.C. 342), as amended by section 4, is amended by adding at the end the following:

- (g)(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).
- (2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.".

9. Conforming Amendments

(a) SECTION 201 - The last sentence of section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended to read as follows: "A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement."

- **(b) SECTION 301 -** Section 301 (21 U.S.C. 331) is amended by adding at the end the following: (u) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.".
- **(c) SECTION 403** Section 403 (21 U.S.C. 343), as amended by section 7, is amended by adding after paragraph (s) the following: "A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.".

10. Withdrawal of the Regulations and Notice

The advance notice of proposed rulemaking concerning dietary supplements published in the Federal Register of June 18, 1993 (58 FR 33690-33700) is null and void and of no force or effect insofar as it applies to dietary supplements. The Secretary of Health and Human Services shall publish a notice in the Federal Register to revoke the item declared to be null and void and of no force or effect under subsection (a).

11. Commission on Dietary Supplement Labels

(a) ESTABLISHMENT. - There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the "Commission").

(b) MEMBERSHIP. -

- (1) COMPOSITION. The Commission shall be composed of 7 members who shall be appointed by the President.
- (2) EXPERTISE REQUIREMENT. The members of the Commission shall consist of individuals with expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacognosy, medical

botany, traditional herbal medicine, or other related sciences. Members and staff of the Commission shall be without bias on the issue of dietary supplements.

(c) FUNCTIONS OF THE COMMISSION. - The Commission shall conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

(d) ADMINISTRATIVE POWERS OF THE COMMISSION. -

- (1) HEARINGS. The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.
- (2) INFORMATION FROM FEDERAL AGENCIES. The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.
- (3) AUTHORIZATION OF APPROPRIATIONS. There are authorized to be appropriated such sums as may be necessary to carry out this section.

(e) REPORTS AND RECOMMENDATIONS. -

- (1) FINAL REPORT REQUIRED. Not later than 24 months after the date of enactment of this Act, the Commission shall prepare and submit to the President and to the Congress a final report on the study required by this section.
- (2) RECOMMENDATIONS. The report described in paragraph (1) shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate.

(3) ACTION ON RECOMMENDATIONS. - Within 90 days of the issuance of the report under paragraph (1), the Secretary of Health and Human Services shall publish in the Federal Register a notice of any recommendation of Commission for changes in regulations of the Secretary for the regulation of dietary supplements and shall include in such notice a notice of proposed rulemaking on such changes together with an opportunity to present views on such changes. Such rulemaking shall be completed not later than 2 years after the date of the issuance of such report. If such rulemaking is not completed on or before the expiration of such 2 years, regulations of the Secretary published in 59 FR 395-426 on January 4, 1994, shall not be in effect.

12. Office of Dietary Supplements

(a) IN GENERAL. - Title IV of the Public Health Service Act is amended by inserting after section 485B (42 U.S.C. 287c-3) the following:

SUBPART 4--OFFICE OF DIETARY SUPPLEMENTS SEC. 485C. DIETARY SUPPLEMENTS.

- **(a) ESTABLISHMENT.** The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.
- **(b) PURPOSE.** The purposes of the Office are -
 - (1) To explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and
 - (2) To promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

- (c) DUTIES. The Director of the Office of Dietary Supplements shall -
 - (1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;
 - (2) Collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine;
 - (3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including -
 - (A) Dietary intake regulations;
 - (B) The safety of dietary supplements;
 - (C) Claims characterizing the relationship between -
 - (i) Dietary supplements; and
 - (ii)(I) prevention of disease or other health-related conditions; and
 - (II) Maintenance of health; and
 - (D) Scientific issues arising in connection with the labeling and composition of dietary supplements;
 - (4) Compile a database of scientific research on dietary supplements and individual nutrients; and

- (5) Coordinate funding relating to dietary supplements for the National Institutes of Health.
- **(d) DEFINITION.** As used in this section, the term "dietary supplement" has the meaning given the term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.
- **(e) AUTHORIZATION OF APPROPRIATIONS.** There are authorized to be appropriated to carry out this section \$5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.
- **(b) CONFORMING AMENDMENT.** Section 401(b) (2) of the Public Health Service Act (42 U.S.C. 281(b)(2)) is amended by adding at the end the following:
- (E) The Office of Dietary Supplements.".

ANNEXURE II

BIBLIOGRAPHY

Introduction

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ANNEXURE III

GLOSSORY

Terminology	Definition
Bioactive com	Naturally occurring chemical com pounds contained in, or derived
pounds	from, a plant, animal or marine source, that exert the desired health
	/wellness benefit.
Functional	Standardized and characterized preparations, fractions or -extracts
ingredients	containing bioactive compounds of varying purity, that are used as
	ingredients, by manufacturers in the food(human and pet) and
	fractions or extracts containing bioactive compounds of varying
	purity, which are used as ingredients by Manufacturers in the
Industrial	cosmetics and pharmaceutical sectors.
	Standardized and characterized preparations, fractions or -extracts of
ingredients	agri-commodities of varying purity that are used as ingredients by manufacturers of non-food products.
Natural Health	Includes homeopathic preparations, substances used in traditional -
Products (NHP)	medicines, minerals or trace elements; vitamins; amino acids;
Troducts (Will)	essential fatty acids; or other botanical, or animal or microoraganism
	derived substances. These products are generally sold in medicinal or
	"dosage" form to diagnose, treat, or prevent disease; restore or
	correct function; or to maintain or promote health.
Traditional Food	Standardized and characterized preparations, fractions or extracts of
Ingredients (TFI)	-agri-commodities of varying purity, that originate from plant, animal
	or marine sources and are used as ingredients, by manufacturers in
	the food (human and pet) and NHP sectors.
Traditional	Conventional foods that have been manufactured by the -traditional
Processed Foods	food processing industry and sold to the public through established
(TPF)	distribution systems for generations.
Traditional	Conventional foods that have been grown by - agricultural producers
Whole Foods	for generations
(TWF)	Foods that naturally contain or are annighed with concer proventing
Designer Foods	Foods that naturally contain or are enriched with -cancer-preventing substances such as phytochemicals(Coined in 1989 by National
	Cancer Institute, USA)
Novel Foods	Products that have never been used as food; foods that result Health
11010110005	Canda (1998) from a processes that has not previously been used for
	food; or, foods that have been modified by genetic manipulation
Nutraceuticals	A product isolated and purified from foods that is generally -sold in
	medicinal forms are usually associated with food. A nutraceutical is
	demonstrated to have a physiological benefitor provide protection
	against chronic disease (Coined originally by Stephen DeFelice in
	1989, founder and chairman of the Foundation for Innovation in
	Medicine, USA)

Functional Foods Phytochemicals /	A functional food is similar in appearance to. Or may be, a -conventional food, is consumed as part of a usual diet, and isdemonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond the basic nutritional functions A nonnutritive bioactive plant substance, such as a flavonoid or
phyto-nutrients	American Heritage® carotenoid, considered to have a beneficial Stedman's Medical effect on human health.
Medical Foods	Special dietary food intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions (Coined in 1992 by the Institute of Food Technologists Expert Panel on Food Safety and Nutrition)
Phyto- pharmaceuticals	Chemicals in their natural from isolated from medicinal plants with potential benefits in human health and disease prevention.
Dietary Supplements	A product that is intended to supplement the diet that bears or contains on or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance, for use by man to supplement the diet by increasing the total daily intake, or concentrate. Metabolite, constituent, extract. Or combinations of these ingredient; intended for ingestion in pill, capsule, tablet, or liquid form; not represented for use as conventional food or as a sole item of a meal or diet; labelled as dietary supplement; includes products such as approved new drug, certified antibiotics, of licensed biologic that marketed as a dietary supplement or food before approval, certification, of license (unless a product is redefined through regulatory government agency)
Enteral Nutrition	It means, "A way to provide food through a tube placed in the nose, the stomach, or the small intestine." A tube in the nose is called a nasogastric or nasoenteral tube. A tube that goes through the skin into the stomach is called a gastrostomy or percutaneous endoscopic gastrostomy (PEG). A tube into the small intestine is called a jejunostomy or percutaneous endoscopic jejunostomy (PEJ) tube. It is also called as tube feeding.

ANNEXURE IV

ABBREVIATION

EFAs-- Omega-3 essential fatty acids

FOSHU--Foods for Specified Health Use

CLA --Conjugated linoleic acid

OTC--Over the counter

VMS—vitamins minerals supplements

FMHG -- Fast moving health goods

FMCG--Fast moving consumer goods

NCDs --non-communicable diseases

FAO's--Food and Agricultural Organization of the United Nations

DARE --Driving Achievement of Retail Excellence

WFDSA --World Federation of Direct Selling Associations

IDSA -Indian Direct Selling Association

DSHEA-- The Dietary Supplement Health and Education Act

FDA-- Food and Drug Administration's

ODS--Office of Dietary Supplements

NIH--National Institutes of Health

EMR - Exclusive Marketing Rights