NUTRACEUTICALS AND DIETARY SUPPLEMENTS MARKETS

SAMPLE COPY, NOT FOR RESALE

Trends, Industry Participants, Product Overviews and Market Drivers
TABLE OF CONTENTS

1. Overview 7
1.1 Statement of Report 7
1.2 Objectives 7
1.3 Scope 7
1.4 Methodology 8
1.5 Executive Summary 9

2. Nutraceuticals and Dietary Supplements Markets 11
2.1 Overview 11
2.1.1 DSHEA Classification 11
2.1.2 DSHEA 11
2.2 Food and Drug Administration Policy 15
2.3 Voluntary Industry Compliance to GMPs 15
2.3.1 Current Progress 16
2.3.2 Future Trends 16
2.4 Key Issues 19
2.4.1 Herbals: Standardized Dosage 19
2.4.2 Vitamin Supplements 19
2.4.3 Mineral Supplements 20
2.4.3.1 PEST Analysis of Vitamin and Mineral Deficiencies in Food 20
2.4.4 Homeopathic Remedies 22
2.4.4.1 Key Issues in Homeopathy 23
2.4.4.2 What Is Homeopathy? 23
2.4.4.3 History 23
2.4.4.4 U.S. Revival of Homeopathy 24
2.4.4.5 Homeopathic Training 24
2.4.4.6 Homeopathic Treatment Regimen 25
2.4.4.7 Homeopathic Remedies 25
2.4.4.8 FDA Regulation of Homeopathic Remedies 25
2.4.4.9 Homeopathy: Side Effects or Complications 25
2.4.4.10 Scientific Research on Homeopathy 26
2.4.4.11 Continuing Homeopathic Controversies 26
2.4.4.12 NCCAM-Funded Research on Homeopathy 27
2.4.5 Essential Oils 27
2.5 Labeling Requirements 27
2.5.1 Nutrient Content Claims 28
2.5.2 Antioxidant Claims 30
2.5.3 High Potency Claims 31
2.5.4 Percentage Claims 32
2.5.5 Health Claims 32
2.5.6 Structure and Function Claims 33

3. Nutraceuticals Market Segments 35
3.1 Overview 35
3.1.1 Market Share 36
3.1.2 World Markets 37
3.1.3 U.S. Market 40
3.1.3.1 U.S. Sales of OTC Healthcare Products 47
3.1.4 Major Markets 47
3.1.5 Asia/Southeast Asia 47
3.1.6 Japan 48
3.1.6.1 Future Trends in the Japanese Market 49
3.1.7 China 49
3.1.8 Taiwan 50
3.1.9 Australia/New Zealand 51
3.1.10 India 51
3.1.11 Western Europe 52
3.1.11.1 Germany 53
3.1.11.2 United Kingdom 53
3.1.11.3 France 53
3.1.11.4 Italy 53
3.1.11.5 Trends in Western Europe 54
3.1.11.6 Market Share 54
3.1.12 Eastern Europe 54
3.1.12.1 Poland 54
3.1.12.2 Russia 55
3.1.13 Middle East 55
3.1.13.1 Turkey 56
3.1.14 Global Trends 58
3.2 Market Trends 59
3.2.1 Market Segments 63
3.2.2 Customer Needs 63
3.2.3 Competitor Analysis 64
3.3 Pricing Pressures 64
3.3.1 "Big Box" Retailing 65
3.3.2 Internet Retailing 65
3.3.3 Mail Order 65
3.3.4 Chain Retail Outlets 65
3.3.5 "Mom and Pop" Health Food Stores 65
3.3.6 Multi-Level Marketing (MLM) 65
3.4 Third-Party Reimbursement 66
3.5 Regulation Trends 66
3.5.1 Food Labeling and Nutrition 67
3.5.2 Dietary Supplements 67
3.5.3 Public Meetings and Hearings 68
3.5.4 Herbs and Botanicals Market: New Opportunities 68
3.5.5 Current Market Dynamics 69
3.5.6 Quality Issues 69
3.5.7 Regulatory Pressures 72
3.5.8 Opportunities 74
3.5.9 Other Opportunities 75
3.6 Advertising 75
3.7 Women's Health 75
3.8 Distribution and Sales 79
3.8.1 Branded Products 79
3.8.2 Mass-Market Sales 79
3.8.3 Health Food Channels 80

4. Technology Issues 81
4.1 Raw Material Variability 81
4.1.1 Realities of Natural Products 81
4.1.2 Source Variability 81
4.1.3 Method of Production/Acquisition Variability 81
4.1.4 Testing Issues 83
4.1.4.1 United States Pharmacopoeia (USP) 83
4.1.4.2 NSF International 84
4.1.4.3 Animal Testing 86
4.2 Production Methods 86
4.3 Change Control: OEM Materials and Production Methods 87
4.4 Cleanliness, Sterilization Methods, Concerns 87
4.5 Categories of Nutraceuticals 87
4.5.1 Aloe Products 87
4.5.2 Amino Acids 87
4.5.2.1 Tryptophan (Essential Amino Acid) 88
4.5.2.2 Lysine (Essential Amino Acid) 88
4.5.2.3 Methionine (Essential Amino Acid) 88
4.5.2.4 Phenylalaine (Essential Amino Acid) 88
4.5.2.5 Threonine (Essential Amino Acid) 88
4.5.2.6 Valine (Essential Amino Acid) 88
4.5.2.7 Leucine and Isoleucine (Essential Amino Acid) 88
4.5.2.8 Arginine (Non-Essential Amino Acid) 88
4.5.2.9 Tyrosine (Non-Essential Amino Acid) 88
4.5.2.10 Glycine (Non-Essential Amino Acid) 89
4.5.2.11 Serine (Non-Essential Amino Acid) 89
4.5.2.12 Glutamic Acid (Non-Essential Amino Acid) 89
4.5.2.13 Asparatic Acid (Non-Essential Amino Acid) 89
4.5.2.14 Taurine (Non-Essential Amino Acid) 89
4.5.2.15 Cystine (Non-Essential Amino Acid) 89
4.5.2.16 Histidine (Non-Essential Amino Acid) 89
4.5.2.17 Proline (Non-Essential Amino Acid) 89
4.5.2.18 Alanine (Non-Essential Amino Acid) 90
4.5.3 Antioxidants 90
4.5.4 Aromatherapy 90
4.5.5 Beauty Products 90
4.5.6 Bee Products 90
4.5.7 Calcium 91
4.5.8 Cardiovascular Health 92
4.5.9 Children's Vitamins and Minerals 92
4.5.10 Coenzymes 93
4.5.11 Colon Products 93
4.5.12 Diet Products 93
4.5.13 Enzymes 93
4.5.14 Eye Care and Nutrition Products 94
4.5.15 Food Supplements 94
4.5.16 Foot Care Products 94
4.5.17 Garlic 94
4.5.18 Green Foods 94
4.5.19 Hair Care Products 96
4.5.20 Herbal Products and Tea 96
4.5.20.1 Alfalfa (medicago sativa) 96
4.5.20.2 Aloe Vera (aloe barbadenis) 96
4.5.20.3 Blessed Thistle 97
4.5.20.4 Burdock Root 97
4.5.20.5 Capsicum or Cayenne (capsicum frutescens) 97
4.5.20.6 Cascara Sagrada or "Sacred Bark" (rhamnus purshiana) 97
4.5.20.7 Chamomile 97
4.5.20.8 Chaparral 97
4.5.20.9 Comfrey 97
4.5.20.10 Echinacea (echinacea angustifolia) 98
4.5.20.11 Euphrasia (euphrasia officinalis) 98
4.5.20.12 Fo Ti (polygonum multiflorum) 98
4.5.20.13 Garlic (allium sativum) 98
4.5.20.14 Ginger (zangiber officinale) 98
4.5.20.15 Ginseng (panax ginseng) 98
4.5.20.16 Gotu Kola (hydrocotyle asiatica or centella asiatica) 99
4.5.20.17 Green Tea Extract 99
4.5.20.18 Hawthorne Berries (crataegus oxyacantha) 99
4.5.20.19 Hyssop 100
4.5.20.20 Licorice 100
4.5.20.21 Ma Huang 100
4.5.20.22 Mullein 100
4.5.20.23 Rose Hips (rosa canina) 100
4.5.20.24 Sarsaparilla (smilax officinalis) 100
4.5.20.25 Saw Palmetto or Pygeum Extract 100
4.5.20.26 Soy Isoflavone Extract 101
4.5.20.27 Spirulina 101
4.5.20.28 St. John's Wort Extract 101
4.5.20.29 Turmeric 101
4.5.20.30 Valerian 101
4.5.20.31 Yellow Dock 101
4.5.21 Homeopathy 102
4.5.22 Minerals 102
4.5.22.1 Calcium 102
4.5.22.2 Magnesium 103
4.5.22.3 Iron 103
4.5.22.4 Iodine 103
4.5.22.5 Chromium 103
4.5.22.6 Copper 103
4.5.22.7 Magnesium, Magnesium Oxide 103
4.5.22.8 Manganese 104
4.5.22.9 Potassium 104
4.5.22.10 Selenium 104
4.5.22.11 Silver, Colloidal 104
4.5.22.12 Zinc 104
4.5.22.13 Trace Minerals 104
4.5.23 Multivitamins 104
4.5.24 Nutritional Oils 105
4.5.24.1 Flaxseed/Linseed Oil 105
4.5.24.2 Black Currant Oil 105
4.5.24.3 Borage Seed Oil 105
4.5.24.4 Cod Liver Oil 105
4.5.24.5 Evening Primrose Oil 105
4.5.24.6 Omega-3/Fish Oils 105
4.5.25 Personal Care Products 107
4.5.25.1 Hyaluronic Acid 107
4.5.25.2 Natural Beauty Soaps 107
4.5.25.3 Creams 107
4.5.26 Vitamins 108
4.5.26.1 Vitamin A (Beta-Carotene) 108
4.5.26.2 Vitamin B-1 (Thiamin) 108
4.5.26.3 Vitamin B-2 (Riboflavin) 108
4.5.26.4 Vitamin B-3 (Niacin) 109
4.5.26.5 Vitamin B-6 (Pyridoxine) 109
4.5.26.6 Vitamin B-12 (Cobalamin) 109
4.5.26.7 Vitamin C (Ascorbic Acid) 110
4.5.26.8 Vitamin D (Calciferol) 110
4.5.26.9 Vitamin E (Tocopherol) 110
4.5.26.10 Pantothenic Acid 111
4.5.26.11 Biotin 111
4.5.26.12 Folic Acid 111
4.5.26.13 Inositol 111
4.5.26.14 Choline 112
8.6 Nutraceutical International Corporation 149
8.7 Perrigo Company 150
8.8 Puritan's Pride 150
8.9 Schiff 151

9. List of Nutraceutical Companies 153

INDEX OF FIGURES

Figure 3.1: U.S. Nutraceuticals Market Product Groups Ranked by Sales: 2005 43
Figure 3.2: U.S. Nutraceuticals Market Product Groups Ranked by Market Share: 2005 44
Figure 3.3: U.S. Top-Selling Vitamins: 2005 44
Figure 3.4: U.S. Sales of Non-Vitamin Nutraceuticals in 2005 45
Figure 4.1: Typical Key Nutraceutical Production Steps 82
Figure 5.1: U.S. Population by Age Clusters 134
Figure 5.2: Representative Major U.S. Producers by Market Capitalization 140

LIST OF TABLES

Table 2.1: Disclosure Statement Requirements Threshold (FDA) 29
Table 3.1: Total World Retail VMS Market: 2002 to 2012 35
Table 3.2: Number of Vitamins/Minerals Consumed per Day by Nutraceutical Consumers 36
Table 3.3: Worldwide Nutraceuticals Market Sales: 2002 to 2012 37
Table 3.4: World Market for Essential Minerals: 2002 to 2012 38
Table 3.5: Vitamins in Nutraceutical Products Market: 2002 to 2012 38
Table 3.6: Worldwide Demand for Herbal and Non-Herbal Extracts: 2002 to 2012 39
Table 3.7: U.S. Nutraceuticals Market Sales: 1999 to 2012 40
Table 3.8: U.S. Natural Foods Market Sales: 2005 to 2012 40
Table 3.9: U.S. Vitamin and Minerals Market Sales: 2005 to 2012 41
Table 3.10: U.S. VMS FDMC Total Market: 2005 to 2012 41
Table 3.11: U.S. VMS FDMC Store Brand Market: 2005 to 2012 41
Table 3.12: U.S. Herbs and Botanicals Market Sales: 2005 to 2012 42
Table 3.13: U.S. Personal Care Market Sales: 2005 to 2012 42
Table 3.14: U.S. Sports Nutrition Market Sales: 2005 to 2012 43
Table 3.15: Market Share of U.S. VMS FDMC Segment 46
Table 3.16: Chinese Dietary Supplements Market: 2002 to 2012 50
Table 3.17: OTC Category Share as a Part of the Total OTC Market: 2005 55
Table 3.18: Import Figures ($ Thousands): 2002 to 2005 57
Table 3.19: Market Drivers: 2006 to 2012 59
Table 3.20: Market Restraints: 2005 to 2012 59
Table 4.1: Organic Foods Categories and Market Share 95
Table 4.2: Total U.S. Organic Food Sales Compared to All U.S. Foods Sales: 1997 to 2005 95
Table 4.3: Foods Most/Least Likely to Be Pesticide-Contaminated 96
Table 5.1: U.S. Healthcare Expenditures 129
Table 5.2: Key Players in U.S. Market 139
1. Overview

1.1 Statement of Report

This report focuses on the world nutraceuticals and dietary supplements markets. The product categories examined include vitamins, minerals, herbal and non-herbal extracts. Additionally, the study reviews measurement methods and resources utilized in the dietary supplements industry. Packed with the latest information relating to new products and industry trends, this analysis not only quantifies but also qualifies the nutraceuticals market in the areas of research, product development and investment opportunities.

1.2 Objectives

The main objectives of this report are to:

- Discuss viable market prospects through the identification of high-growth opportunities in different nutraceuticals and dietary supplements areas.
- Focus on global dietary supplements industry development through an in-depth analysis of the major world market, including forecasts for growth.
- Examine the use of nutraceuticals and dietary supplements in pharmaceutical drug development, with examples of its use in the development and repositioning of therapeutic agents.

This examination covers the following categories of nutraceuticals and dietary supplements segments:

- Role of nutraceuticals in dietary changes.
- Barriers to nutraceuticals use.
- Drivers of nutraceuticals use.
- Business trends in the industry.
- Important technology trends in nutraceuticals.

This study contains the latest information on the nutraceuticals and dietary supplements market in the United States. It includes information on the products that compose this industry, descriptions, RDA (recommended daily allowances) where established, common dosages, packaging and quantities. Also included are:

- A comprehensive overview of one category of nutraceuticals that is—or will be—revolutionizing the treatment of cardiovascular diseases.
- Full descriptions of the technologies involved and how these differ from the existing and emerging technologies.
- Analysis of the approaches undertaken by various competitors in the industry and end-user responses to these products.
- Regulatory issues and legislation affecting the use and marketing of nutraceuticals products.

1.3 Scope

The emphasis in this report is on those companies that are actively engaged in developing and marketing nutraceutical and dietary supplement products. The reader should consult other TriMark reports at http://www.trimarkpublications.com for a detailed discussion of the important individual market segments that are related to the nutraceutical market, such as molecular diagnostic testing, clinical chemistry, cancer testing, infectious disease markers and other exciting new diagnostic methods. What’s more, this examination defines the dollar volume of sales in the U.S. market and analyzes the factors that influence the size and growth of the market segments. The study surveys all companies known to be marketing, manufacturing or developing nutraceutical technologies in the U.S. for the selected segments. Effort has also been made to include sections on smaller companies located around the world.
1.4 Methodology

This review is based upon interviews with sales and marketing professionals of companies in the nutraceuticals market. They were queried, some several times, about their companies’ products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with CEOs and vice presidents of some of the companies discussed in the report.

Sources of information for the study were trade association publications and meetings, product brochures, and catalogs and company literature. Where the companies under discussion were publicly held, an examination of the annual reports, 10k filings and financial reports were used as the basis of the data reported. Important data sources include the Health for All Database of the World Health Organization, data published by the statistical office of the European Communities (Eurostat), as well as various health data from the United Nations and the Organization for Economic Cooperation and Development. Where possible and practicable, the most recent data available have been used. Some e-information was obtained from national government institutions, while economic forecasts are based on the latest predictions published by the International Monetary Fund’s economic analysis unit.

The author of this report is a Ph.D. with decades of experience in science writing and as a medical industry analyst. The senior editor has many years of experience in clinical science, as well as extensive experience in senior-level positions in biotech, pharma and medical service companies. Some of the statistical information was taken from Biotechnology Associates’ databases (a global information and consulting company specializing in analysis of biotech and medical information) and from TriMark’s private data stores. The information set forth in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information, omission or for the results obtained by the use of such information.

Primary Sources: TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark’s research of the past three years as part of this data collection. We also extract qualified data feeds from questionnaire responses and primary research responses for this compilation.

Secondary Sources: TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, Investment Research Reports, Trade and Industry Association reports, government-affiliated trade releases, and other published information as part of our secondary research materials.

The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations. The report conclusions are verified through intensive interviewing of top-ranking companies in the industry.

TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly available databases, proprietary databases, direct meetings and personal interviews with key personnel.

- Formulating a study outline with the assigned writer, including important items:
  - Market and product segment grouping and evaluating its relative significance.
  - Key competitors evaluations including its relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
  - End-user research to evaluate analytical significance in market estimation.
  - Supply chain research and analysis to identify any factors affecting the market.
  - New technology platforms and cutting-edge applications.
• Identifying the key technology and market trends that drive or affect these markets. Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.

• Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific and region-specific communications to qualified and experienced senior executives worldwide.

• Completing a confirmatory primary research assessment of the report’s findings with the assistance of expert panel partners from the industry being analyzed.

1.5 Executive Summary

Dietary supplements consist of vitamin and mineral supplements. They also include herbs, aromatherapy, essential oils, enzymes, and homeopathic and similar naturally-derived substances, excluding tobacco.

World Markets:

The total global retail natural products market is highly fragmented and totaled approximately $52.6 billion in retail sales in [ ]. Key components of this market, comprising over two-thirds of the entire global market, consist of the following sub-markets:

- Vitamins, minerals and supplements (VMS): $22.0 billion
- Essential minerals: $7.3 billion
- Vitamins in other products: $4.1 billion
- Herbal / non-herbal extracts: $1.5 billion

The total world retail VMS portion of the global nutraceutical market itself is highly fragmented with sales of $22.0 billion in [ ], which is now growing at a compound annual growth rate (CAGR) of approximately [ ]%. The projected growth to [ ] is $30.5 billion. The nutraceutical and dietary supplement industry benefits from a steadily increasing global demand for nutritional preparations, natural medicines, functional foods, as described in the body of this report, which is growing at an overall CAGR of about [ ]%.

The global demand for essential minerals (stand-alone products) is worth $7.3 billion, and—with a CAGR of [ ]%—it is expected to reach $10.7 billion in [ ]. Another segment of the worldwide demand for vitamins is their inclusion in other nutraceutical products, e.g., personal care products, which was worth $4.1 billion in [ ], and estimated to grow at the rate of [ ]% annually to touch $5.2 billion in [ ]. The market for herbal and non-herbal extracts is $1.5 billion. Their increasing acceptance by consumers and medical professionals will see the worldwide demand for herbal and non-herbal extracts growing by [ ]% annually to $2.3 billion in [ ].

U.S. Markets:

The U.S. represents a $20.7 billion market in [ ] (up from $14.7 billion in [ ]) in nutraceutical products. Growing at a CAGR of [ ]%, it is projected to grow to $24.2 billion by [ ]. Principal sub-categories consist of the following:

- Vitamins, minerals and supplements (VMS): $6.7 billion
- VMS FDMC: $4.3 billion
- Herbs and botanicals: $4.1 billion
- Personal care products: $3.4 billion
- Sports nutrition: $1.6 billion
- Other: $0.6 billion

As indicated above, this U.S. market figure is composed of a $6.7 billion market in vitamins, minerals and supplements. Growing at a CAGR of [ ]%, it is estimated to reach $7.7 billion by [ ]. The U.S. represents a $
The market in the additional VMS food, drug, mass merchant and warehouse club (FDMC) segment, which is now growing at a CAGR of approximately $\Box\%$. It is projected to grow to $\Box$ billion in $\Box$. This figure also includes a sub-category, a $\Box$ billion market for VMS FDMC store brand (versus name brands, but usually manufactured by the same companies) products. It is now growing at a CAGR of approximately $\Box\%$. The projected growth to $\Box$ billion is $\Box$ billion.

Included in the overall U.S. figure is a $\Box$ billion market in herbs and botanicals products, which is growing at a CAGR of approximately $\Box\%$. The projected growth to $\Box$ billion is $\Box$ billion. Another category, the market for personal care products in the U.S. currently stands at $\Box$ billion. Growing at a CAGR of approximately $\Box\%$, it is projected to grow to $\Box$ billion by $\Box$. The U.S. also represents a $\Box$ billion market in sports nutrition products. The projected growth to $\Box$ billion is $\Box$ billion.

**Market Drivers**

- Aging population, especially the “baby boom” generation reaching active retirement, combined with the changing consumer demographics. Americans are living longer and emphasizing the importance of quality of life in their later years. As the baby boomers approach ages where personal health becomes more paramount, the demand for mechanisms for enhancing health will grow.

- Acceptance of dietary supplements as food additives is growing with labeling contributing toward increasing public awareness of supplements and their benefits.

- Acceptance of “self-medication,” “wellness” and “healthy lifestyle” among individuals and companies for their employees and, with some, for their retirees.

- Concerns about the growing healthcare costs at the individual and/or company level are driving some “wellness” programs.

- Media publicity has been a mixed bag with many contradictory articles on studies.

- A paradigm shift in personal health: Americans are taking more responsibility for their personal health, embracing the concept of health maintenance and wellness. Thus, the paradigm is shifting away from disease treatment and towards disease prevention.

- Dissatisfaction with western healthcare: Americans are becoming more reticent about accepting the side effects of synthetic drugs and remedies. Similarly, rising healthcare costs are encouraging Americans to explore alternatives to traditional medicine.

- Increasing acceptance of alternative healthcare practices: There is a growing acceptance among Americans of alternative or complementary therapies and wellness modalities. Recent years have witnessed increased use, for example, of chiropractic care, vitamin therapy, aromatherapy, meditation and relaxation techniques, and acupuncture.

- Better understanding and awareness of diet-disease relationships: Many of the leading causes of premature death are diet-related. Examples include heart disease, diabetes and many types of cancer.

**Market Restraints**

- Cost factors, where many products are viewed as commodities.

- Mainstream medicine’s reluctance to be inclusive of alternative paths.

- Past-exaggerated claims make consumers leery.

- Limited brand loyalty toward generic products viewed as a commodity.

- Negative publicity from issues discussed in this report, e.g., contaminations of raw material, sterilization issues, et al., which can be mitigated by increasing adoption and use of voluntary quality systems.