

The Market For Medical Foods

Market Potential, Demand, Competitors

July 2015

Table of Contents

<u>Introduction & Study Scope</u>	Page
Explanation of the various sources used in the research of this market, and the scope of the report.	1-5
<u>Executive Overview of Major Findings</u>	6-12
Summary of all report chapter highlights. Discussion of medical foods definition, industry structure, what conditions medical foods are used for, major issues & trends affecting the market, end-user demand, market size and 2020 forecasts, outlook by mfrs., distribution channels, major competitors.	
<u>Market Nature and Definition: what are medical foods?</u>	13-25
<ul style="list-style-type: none">• Definition of medical foods by the FDA• History and evolution of the products since the 1950s• Diseases and medical conditions targeted• End-users• New Product Development Process – discussion.• Market position in the healthcare space• Reimbursement for Medical Food Prescriptions: private insurance, workmen's compensation insurance.	

Products: The main brands

Descriptions of products and their intended uses:

- Axona (Accera)
- Limbrel (Primus Pharmaceuticals)
- Deplin (Pamlab)
- Lofenalac (Mead Johnson Nutrition)
- Neurepa
- Immunolin

Table: Sample of Medical Foods Currently Sold & Their Targeted Diseases

End-User Markets & Demand Factors

26-38

- Summary & discussion of main drivers of demand
- Aging of the U.S. population – discussion of prevalence of chronic diseases associated with aging, to 2030 (Parkinsons, diabetes, hypertension, heart disease).
- Shift to enteral nutrition.
- Demand for customized medicine
- PTSD – discussion of, no. of sufferers
- Depression - discussion of, no. of sufferers
- Osteoporosis - discussion of, no. of sufferers
- Chronic pain - discussion of, no. of sufferers
- Insomnia - discussion of, no. of sufferers
- Kidney disease - discussion of, no. of sufferers
- Necrotizing enterocolitis in low birthweight infants - discussion of, no. of sufferers
- Alzheimer’s - discussion of, no. of sufferers
- Obesity - discussion of, no. of sufferers
- Fibromyalgia - discussion of, no. of sufferers.

Tables:

- U.S. population projections, by age group: 2015-2050
- Population by percentage of the population: 1900 -2060
- Estimated Number of Americans With Conditions That Can Be Treated With Medical Foods: 2015

How Providers of Medical Foods Operate

39-41

- Discussion of the manufacturing process, how medical foods get from the mfr. to the retail pharmacists and other healthcare facilities.
- Typical profit margins, mark-ups.
- Average wholesale prices
- Pharmacist entrepreneurs.
- Reimbursement.
- On-site point-of-care dispensing, cash & carry programs.

Market Size & Growth, Forecasts

42-46

- Estimates by several research companies of the market's size and growth rates, factors affecting demand, estimated revenues for 2011, 2015, 2016, 2020 Forecast. Estimates by: BioStrategies Group, Technology Catalysts, and Marketdata.
- Global market size estimate.
- Outlook for the industry by several manufacturers: obstacles to growth, positive and negative factors.

Functional Food Trends

- Discussion of functional foods and nutraceuticals, usage by consumers for Various conditions, consumer attitudes toward these products.

Distribution Channels & Target Markets

47-53

- Summary: discussion of how medical foods are distributed from the manufacturers to pharmacies, physicians and the patient.
- Profiles of 3 distributors: Samia, Emerson Ecologics, Xymogen.

Tables: Industry snapshots (Census data: no. of establishments, annual revenue per estab., payroll & sales per employee, etc. 1997, 2002, 2007, 2012 revenues) for:

Retail pharmacies

Mail order pharmacies

Hospitals

Long term care facilities, nursing homes

Primary care MDs & specialist MDs offices

Prescribing nurses

Registered dietitians

Home health care services

Specialized disease clinics

Government Regulation of Medical Foods

54-57

- Discussion of FDA regulation and monitoring of medical foods, Orphan Drug Act of 1984, timeline of key developments and actions
- Enforcement: Warning Letters from FDA citing medical food issues, actions against various firms.
- Recently issued Medical Food Guidance/Q&A document.
- Insurance coverage, lack of it, not covered by Affordable Care Act.
- 2009 Medical Foods Equity Act – discussion.

Competitor Profiles

58-88

(company headquarters address, company history, products made and in development, specializations, acquisitions, revenues when available for public companies).

- Abbott Labs
- Actavis PLC (Ireland)
- Acasti Pharma (Canada)
- Aptalis Pharma
- Cambrooke Therapeutics
- Centrix Pharmaceuticals=
- Entera Health
- Entia Biosciences
- Fresenius Kabi AG
- Geneden Biotech
- Laser Pharmaceuticals
- Mead Johnson Nutrition Co.
- MetaGenes
- Metagenics
- Microbiome Therapeutics
- NattoPharma ASA (Norway)
- Nestle Health Sciences (Pamlab, Accera, Prometheus Labs)
- Nutricia North America
- NVN Therapeutics
- Phytomedics
- Pivotal Therapeutics
- Primus Pharmaceuticals
- Proliant Health & Biologicals
- Prismic Pharmaceuticals
- Realm Labs LLC
- Sigma-Tau Pharmaceuticals
- SKIM (Netherlands)
- Spherix
- Targeted Medical Pharma
- Valeant Pharmaceuticals
- Vaya Pharma

Reference Directory of Market Information Sources

89-91

Directory of relevant trade associations, reports, experts, published articles, other sources.

