

Medical Foods in North America: Regulations,
Industry Landscape and Innovation
北美医用食品法规，产业概况与创新

创新驱动特殊膳食食品全产业链发展国际论坛
暨联盟特医食品产业科技创新专业委员会成立活动

Xi'an, China August 4, 2017

Michael ZC Li, MD, MSc, MBA

Adjunct Professor
Food, Nutrition & Health (FNH)
Western Nutrition Research Centre (WNRC)
The University of British Columbia (UBC)

Managing Director
Wellgenex Sciences Inc.



Vancouver, Canada



Presentation Outline 内容纲要

- A. Regulations 法规**
 - i. United States 美国
 - ii. Canada 加拿大
- B. Market Dynamics and Industry Profile 市场动向和行业概况**
 - i. Size, scope, trend and channel 规模, 趋势和渠道
 - ii. SWOT analysis 态势分析
 - iii. Select company and product profile 公司和产品展示
- C. Wellgenex/WNRC/UBC Introduction 公司与大学平台简介**
- D. Q & A 问答**

A. Regulations-Other Names of Medical Foods 法规 - 医用食品其他相应名称

Country/Organization	English	Chinese
The Codex Alimentarius Commission (CAC)	Foods for Special Medical Purpose	特殊医学用途食品
European Union (EU)	Dietary Foods for Special Medical Purpose	特殊医学用途膳食食品
U.S.	Medical Foods	医用食品
Canada	Foods for Special Dietary Use	特殊膳食食品
Australia	Foods for Special Medical Purpose	特殊医学用途食品
Japan	n/a (in Japanese)	病人用特别用途食品
China	Foods for Special Medical Purpose	特殊医学用途配方食品

A. Regulations – United States 美国法规

History and Milestones 发展历程

- ❑ 1938 – US Federal Food, Drug & Cosmetic Act passed to law
- ❑ 1941 - Foods for Special Dietary Use (FSDU) 特殊膳食食品 proposed by FDA
- ❑ 1972 - FSDU first regulated as drugs till 1972
 - ❑ Lofenalac - infant formula for PKU by Mead Johnson in 1957
 - ❑ Removed from drug and regulated as FSDU in 1972. Premarket approval no longer required
- ❑ 1988 - Medical Foods 医用食品 created by Orphan Drug Amendments of 1988
 - ❑ A food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.
- ❑ 1990 – Nutrition Labeling and Education Act
 - ❑ Further distinguished from conventional foods



A. Regulations – United States 美国法规

Characteristics and Statutory Definition of Medical Foods

医用食品的法定定义及特征

- Specially formulated and processed (as opposed to a naturally occurring foodstuff used in its natural state) for patients for oral or enteral administration;
- Patients must have limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary food or certain nutrients;
- Specific dietary management of a disease cannot be achieved by the modification of the normal diet alone;
- Intended to provide dietary management for specific disease or condition with distinctive nutritional requirements;
- As an integral part of the clinical treatment of patients intended to be used under the active and ongoing medical supervision.

A. Regulations – United States 美国法规

FDA Guidance for Industry and Enforcement FDA行业指南与执行

- ❑ FDA regularly issues/updates guidance. Recommendations only, not legally binding
- ❑ Warning letters issued by FDA started 2001
- ❑ Diseases or conditions considered ineligible for treatment and/or maintenance with medical foods:
 - Chronic fatigue syndrome, fibromyalgia, leaky gut syndrome, metabolic syndrome, cardiovascular disease, inflammatory bowel disease and/or conditions, **Type 2 diabetes**, atopic disorders such as eczema, rhinitis, and allergy-responsive asthma, bariatric patients pre- and post-operatively, and peripheral artery disease
- ❑ Diseases or conditions not considered inappropriate for treatment and/or maintenance with medical foods:
 - Inflammatory conditions, migraines, immune system deficiencies, Alzheimer's disease, arthritis, colitis, constipation, lactose intolerance, diarrhea, chronic illnesses, failure to thrive, pre/post-surgery conditions, and vitamin deficiency throughout **pregnancy**, postnatal, and the lactating periods.
 - ❑ Reasons by FDA: 1) there was inadequate evidence that the disease had distinct nutritional requirements; 2) there was inadequate evidence that the particular food at issue would meet the distinct nutritional requirements; and/or (3) there was no available evidence illustrating that the nutrient levels cannot be achieved by diet modification alone.

A. Regulations – United States 美国法规

Distinction b/w Drugs, Medical Foods & Dietary Supplements 医用食品与药及膳食补充剂的区别

	Drugs	Medical foods	Dietary supplements
Governing regulation	Federal Food, Drug and Cosmetic Act	Orphan Drug Act (amendments, 1988)	Dietary Supplements Health & Education Act
IND required	Yes	No	No (needed for health claims)
Pre-market scientific testing	Preclinical and clinical studies (phases I, II, III)	Medical evaluation in patients with the specific disease being targeted	No
Ingredients	Mostly synthetic, can be nutritional	Nutritional, not in ordinary diet	Nutritional
NDA/BLA required	Yes	No	No
Claims	Negotiated with FDA and dependent on pivotal clinical trial data	Dietary management of a specific disease	Support healthy function
Intended target population	Diseased - for patients with a specific indication or symptoms	Diseased - for meeting nutritional requirements of a specific diseased population	Normal, healthy adults
Safety and pharmacovigilance	Need to establish through clinical trials and post market surveillance	GRAS and post market surveillance	General expectation of safety and through monitoring of consumer complaints
Physician supervision	Required if prescription drug, not for OTC medications	Required	None
Dosing	Any	Oral or enteral	Oral
Distribution	Hospitals, retail pharmacies	Hospitals, retail pharmacies	Health food stores, mass market

Source: R. Pullon. An introduction to the medical foods industry. 2013

A. Regulations – Canada 加拿大法规

- Regulated as Foods for Special Dietary Use (FSDU) 特殊膳食食品
 - A food that has been specially processed or formulated to meet the particular requirements of a person:
 - a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury; or
 - b) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods.
- Product representation:
 - Formulated liquid diet
 - A meal replacement
 - A nutritional supplement
 - A gluten-free food
 - A food represented as:
 - a protein-restricted diet,
 - a low-amino acid diet, or
 - a very low-energy diet.
- Distinct from drugs, novel foods and natural health products
- Premarket assessment/approval (e.g. TMA) may be encouraged or required

B. Market Dynamics and Industry Profile 市场和行业概况

Size, Scope, Trend and Channel 规模, 趋势和渠道

- Size and scope: 规模
 - Difficult to estimate
 - US\$3 billion reported in the US (2015); \$300 million (?) in Canada
 - 23 companies with 82 products in the US (2013)
- Trend: 趋势
 - Rapid growth since late 1990's as nutrition knowledge grew dramatically
 - Movement to mainstream medical use
 - New players from other industries (e.g. supplement companies)
 - Online ordering starting to occur
- Major channel: 主要渠道
 - Hospitals
 - Nursing homes
 - Home care agencies

B. Market Dynamics and Industry Profile 市场和行业概况

List of Some Major Companies 一些主要医用食品公司名列

Abbott Laboratories

Accera

Alfasigma (formerly PamLab,
Pam American Labs)

Axcan Pharma

Bioenergy

Efficas

Ganeden Biotech

Garden of Life

Mead Johnson

Metagenics

Nestlé

NeuroScience

Nutraceuticals / Danone

Primus Pharmaceuticals

Targeted Medical Pharma

Upsher-Smith

Vitafli

B. Market Dynamics and Industry Profile 市场和行业概况

SWOT Analysis 态势分析

- Strengths and key growth drivers 优势和增长驱动力:
 - Increase in aging population (≥ 65 yr population 15.3% in the US and 18.2% in Canada in 2016) and increased life expectancy
 - Higher incidence of chronic disease
 - Shift to enteral nutrition from parental nutrition
 - Demand of personalized medicine
 - Government involvement (e.g. reimbursement)

- Weakness / Challenges 劣势/挑战:
 - Resources for R&D and product development including clinical trials
 - Time to gather medical evidence
 - Communication with healthcare professionals and government agencies
 - Lack of awareness and understanding for medical food in the medical community and in the general public
 - Overlap with supplements and other nutritional products
 - Cost of medical foods not covered by all health services and insurers

B. Market Dynamics and Industry Profile 市场和行业概况

SWOT Analysis 态势分析

- Opportunities 机会:
 - Drugs alone can't succeed completely in treating disease besides side effects
 - Medical foods are less cost and quicker to market
 - Medical foods are safer as produced from GRAS ingredients
 - Advance in the science of nutrition and disease, and in food technology (e.g. microencapsulation).
- Threats 威胁:
 - Market currently dominated by a small # of large companies
 - Established market channels and share
 - Large patent portfolios limit new innovators
 - Competition with other nutrition and food as well as drug companies
 - Increasing FDA enforcement
 - Shifting in facility types from in-patient hospital care to home care

C. Select Companies and products 公司和产品概述

Product Categories 产品范畴

1. Nutritionally Complete Products 全营养产品

- ❑ Usually contain a protein source, carbohydrate source, and fat source with possible vitamins, minerals or electrolytes
- ❑ Taken as a complete food. No need to be supplemented with other food sources
- ❑ Most commonly used for patients on tube feeding

2. Nutritionally Incomplete Products 非全营养产品

- ❑ Contain a single food group, such as carbohydrates only or vitamins only
- ❑ Need to consume additional food sources for a complete diet
- ❑ May be taken by patients who are at home and still able to eat normal foods

3. Formulas for Metabolic (Genetic) Disorders 代谢性(遗传性)疾病

- ❑ Treat metabolic disorders by targeting signalling pathways
- ❑ Formulas typically with unique nutrients removed or added

4. Oral Rehydration Solutions 口服补液

- ❑ Help the body absorb nutrients by shifting oral solution osmolarity for GI tract to retain fluid
- ❑ Typically contain sodium, chloride, potassium citrate, dextrose and water

C. Select Companies and products 公司和产品概述

Some Currently Available Products 市场上现有的一些产品



Trade Name	Disease or Chronic Condition	Health Claim
Cerefolin NAC	Mild to moderate cognitive impairment with or without vitamin B12 deficiency, vascular dementia, or Alzheimer disease	Dietary management of patients being treated for early memory loss, with emphasis on those at risk for neurovascular oxidative stress and/or hyperhomocysteinemia
Axona	Alzheimer disease	Management of metabolic processes associated with mild to moderate Alzheimer disease
Vasculera	Chronic venous insufficiency	Clinical dietary management of the metabolic processes of chronic venous insufficiency
Fosteum PLUS	Osteopenia and osteoporosis	Clinical dietary management of the metabolic processes of osteopenia and osteoporosis
EnteraGam	Chronic loose and frequent stools	Clinical dietary management of the nutrient needs of patients with chronic loose and frequent stools (IBS-D, IBD, HIV-associated enteropathy, malnutrition)
Modulen IBD	Crohn's disease	For use as a sole source of nutrition during the active phase of Crohn's disease and for nutritional support during the remission phase
VSL#3	IBS-D and pouchitis	Clinical dietary management of IBS-D and pouchitis
Vivonex	Severe protein or fat malabsorption, transitional feeding, extensive bowel resection, malabsorption syndrome, select trauma/surgery, early postoperative feeding, intestinal failure, pancreatitis, chylothorax, trophic feeding, TPN alternative, dual feeding with TPN	For nutritional support of those with severe gastrointestinal impairment



IBD, inflammatory bowel disease; IBS-D, diarrhea-predominant irritable bowel syndrome; TPN, total parenteral nutrition.

Source: P. Ciampa. *Gastroenterology & Hepatology* 13(2):104-115, 2017

C. Select Companies and products 公司和产品概述

EnteraGam

- ❑ Entera Health, Inc., Cary, NC, USA
- ❑ Introduced in the US in 2013
- ❑ Net sales \$5 million in the US in 2016
- ❑ Product:
 - A serum-derived bovine immunoglobulin/protein isolate (SBI) that binds microbial components such as toxic substance released by bacteria that upset the intestine environment
 - A unique mechanism of action to restore gut balance
 - Has been studied for various uses:
 - ❑ Diarrhea-predominant irritable bowel syndrome (IBS-D)
 - ❑ Inflammatory bowel disease (IBD)
 - ❑ Human immunodeficiency virus (HIV)-associated enteropathy



C. Select Companies and products 公司和产品概述

Fosteum PLUS

□ Primus Pharmaceuticals, Inc., Scottsdale, AZ, USA

□ Product:

■ Formula (each capsule contains):

Calcium	500 mg
Phosphate	70 mg
Genisten aglycone	27 mg
Citrated zinc bisglycinate	20 mg
Trans-menaquinone-7(vitamin K2)	90 mcg
Cholecalciferol (vitamin D3)	400 IU

■ Dosage: 1 capsule x b.i.d.

■ Dietary management of the metabolic processes associated with osteopenia and osteoporosis

■ Indicated when a healthy diet and supplements such as calcium and vitamin D not enough, but not willing to take drugs



C. Select Companies and Products 公司和产品概述

Vivonex

- Nestlé Healthcare Nutrition, Inc., Bridgewater, NJ, USA
- Product:
 - Vivonex T.E.N. (3% fat)
 - Vivonex PLUS (6% fat)
 - Vivonex RTF (10% fat, tube feed only)
 - Vivonex Pediatric (25% fat)
- An elemental formulation of free amino acids with low levels of fat to help with gastric emptying and minimize pancreatic stimulation
- For patients with severely impaired gastrointestinal function



□ Corporate highlight:

- A Canadian professional firm focusing on medical, nutrition and natural health in North America and Asia Pacific
- Experts with extensive expertise in academia, industry and agencies bridging the gap between science and business

□ Area of specialty:

- New market entry, due diligence, strategic alliance
- R&D, product development and commercialization
- Scientific & regulatory affairs

Helping you create product excellence and connect to market success



D. FNH/WNRC/UBC (不列颠哥伦比亚大学)简介

- 1908 established
- Consistently ranked in the top 3 in Canada and 40 (22nd-34th) universities worldwide
- Notables – 4 Canadian prime ministers, 7 Nobel laureats, 67 Rhodes Scholars, 63 Olympic awards
- 12 faculties – FNH is under Faculty of Land and Food Systems
- FNH/UBC - one of the 17 universities in Canada with accredited dietetic programs; one that offers both undergraduate and graduate programs
- WNRC – offers contract research services in human clinical trials, glycemic index (GI) testing, sensory evaluation, laboratory services, regulatory affairs, etc.







D. Q & A 问答



Michael ZC Li, MD, MSc, MBA

Tel: +1-604-800-2938

Email: mli@wellgenex.com

michael.li@ubc.ca

Web: www.wellgenex.com

www.wnrc.landfood.ubc.ca