

Foods for Special Medical Purposes and Use of Their Liquid Products in North America

北美特殊医学用途配方食品及其液体流食产品的一些应用交流

特医液体产品在国内外的应用
2017新行业, 新机遇 – 特医行业的浪潮

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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. Other Names of Medical Foods 医用食品其他相应名称

Country/Organization	English	Chinese
The Codex Alimentarius Commission (CAC), FAO-WHO/UN	Foods for Special Medical Purposes ((FSMP)	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
USA	Medical Foods	医用食品
Canada	Foods for Special Dietary Uses	特殊膳食食品
Australia	Food 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 Purposes (FSMP)	特殊医学用途配方食品

A. History and Milestones - USA 美国发展历程

- ❑ 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** 婴儿特别营养配方 - infant formula for PKU (苯酮尿症) by **Mead Johnson** (美赞臣) 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
- ❑ 1990 – Nutrition Labeling and Education Act
 - ❑ Further distinguished from conventional foods



A. Canada 加拿大

- Regulated as Foods for Special Dietary Uses (FSDU) 特殊膳食食品
- Product representation:
 - Formulated liquid diet 配方流食
 - A meal replacement 代餐
 - A nutritional supplement 营养补充
 - A gluten-free food 无麸质食品
 - A food represented as: 其他特膳食品
 - a protein-restricted diet, 蛋白质限制
 - a low-amino acid diet, or 低氨基酸
 - a very low-energy diet. 低能量
- Distinct from drugs, novel foods and natural health products
- Premarket assessment/approval (e.g. TMA) may be encouraged or required

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

- Size and scope: 规模
 - US\$3 billion reported in the US (2015) and \$9.7B worldwide (2010)
 - 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 医院
 - Nursing homes 养老院
 - Home care agencies 居家护理机构

B. List of Some Major Companies 主要特医公司

Abbott Laboratories 雅培

Accera

Alfasigma (formerly PamLab,
Pam American Labs)

Axcan Pharma

Bioenergy

Efficas

Ganeden Biotech

Garden of Life

Mead Johnson 美赞臣

Metagenics

Nestlé 雀巢

NeuroScience

Nutraceuticals / Danone 纽迪希亚/达能

Primus Pharmaceuticals

Targeted Medical Pharma

Upsher-Smith

Vitafli

C. Product Categories – Liquid FSMP 特医液体产品分类

A. Oral Nutritional Supplements (ONS) 口服营养补充

- ❑ For patients with functional GI and swallowing (via oral)

a) Standard Liquid (Milkshake Style)

- ❑ Nutritionally complete 全营养
- ❑ Lactose-free suitable for patients intolerant to lactose

b) Clear Liquid (Juice Style)

- ❑ Nutritionally incomplete 非全营养; used only if patient dislikes milky drinks
- ❑ Fat-free suitable for patient requiring fat-free diet (e/g. pancreatitis)

B. Enteral Nutrition 肠内营养

- ❑ For patients with functional GI but unable to swallow (via tube feeding)

a) Standard/Fibre-containing Formulas 标准配方

- ❑ Nutritionally complete 全营养
- ❑ Usually lactose-free and isotonic (caloric density 1-2 kcal/ml)

b) Elemental/Semi-elemental Formulas 初形/半初形配方

- ❑ Pre-digested nutrients, lactose- and fibre-free, moderately to highly osmotic

c) Specialized Formulas 特殊配方

- ❑ Metabolic (genetic) disorders, diabetes, pulmonary, renal, hepatic, immune-enhancing, etc.

D. Indications 适应症

- ☑ Short bowel syndrome
- ☑ Inflammatory bowel
- ☑ Dysphagia
- ☑ Disease-related malnutrition
- ☑ Pre-operative preparation for undernourished patients
- ☑ Continuous ambulatory peritoneal dialysis (CAPD)
- ☑ Intractable malabsorption
- ☑ Following total gastrectomy
- ☑ Bowel fistula
- ☑ Haemodialysis

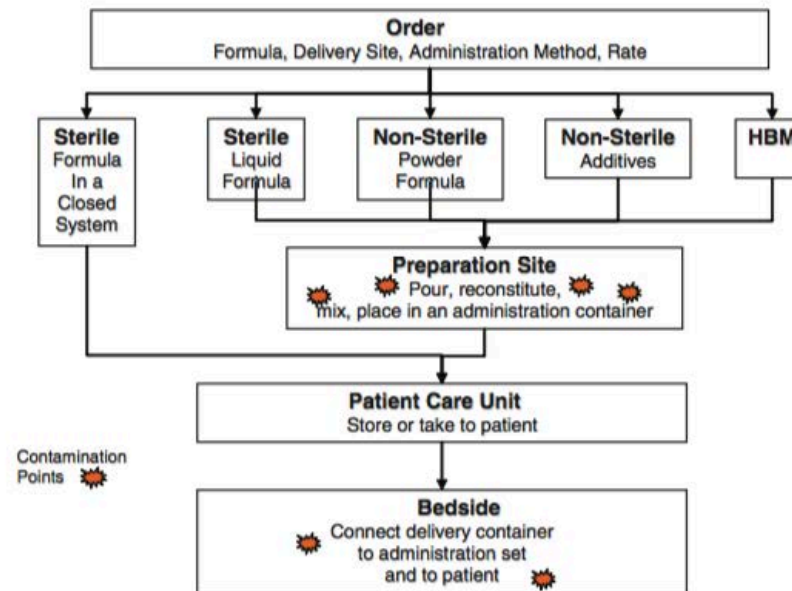
D. Contraindications 非适应症

- ❑ Non-operative mechanical GI obstruction 非手术机械性胃肠道阻碍
- ❑ Intractable vomiting or diarrhea 难治性呕吐或腹泻
- ❑ Short bowel syndrome 短肠综合症
- ❑ Paralytic ileus 麻痹性肠梗阻
- ❑ Distal high-output fistula 末端高输出瘻
- ❑ Severe GI bleed resulting hemodynamic instability 严重胃肠道出血导致不稳定血象
- ❑ Severe malabsorption 严重吸收不良
- ❑ Inability to gain access to the GI tract 不可夠取胃肠道
- ❑ Expected need less than 5-7 days if malnourished or 7-9 days of adequately nourished 预计营养支持需求少于5-7天的营养不良者，或少于7-9天充足营养者
- ❑ Aggressive therapy not warranty or desired by patient or proxy 不需积极治疗

E. Liquid Vs. Powdered 液体相比粉剂

- Medically required 医疗需用
- Non-liquid products bacteria contamination in preparation 非液体产品配备中细菌污染问题
 - 30%-57% formulas prepared in hospitals found contaminated
 - >80% formulas prepared at homes found contaminated

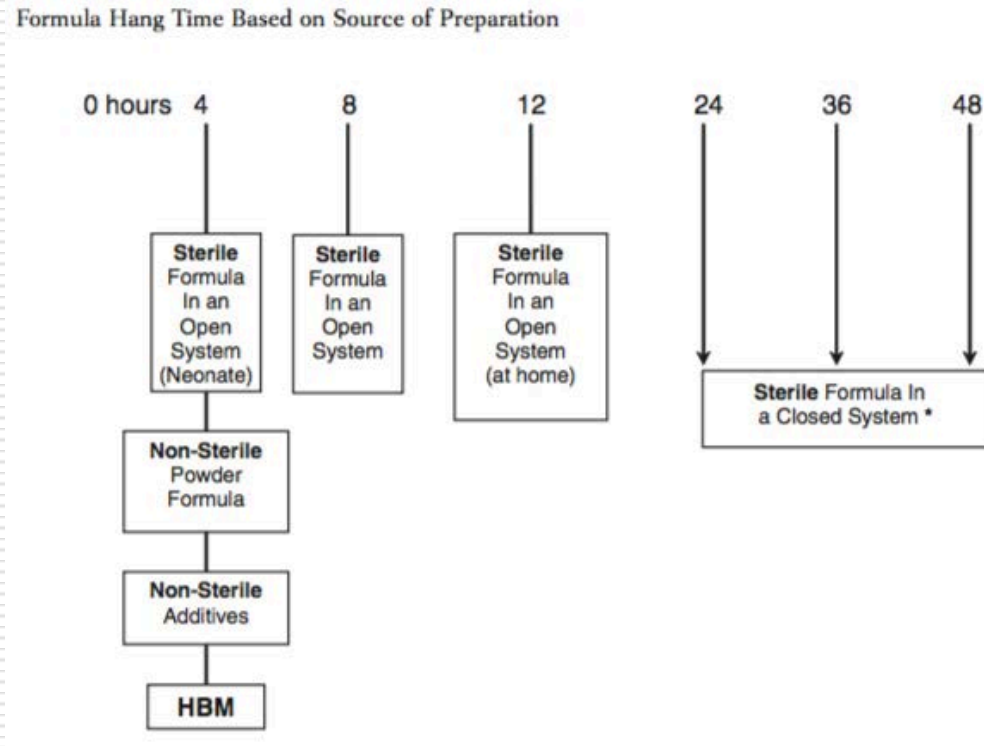
Potential Points for Contamination in the Preparation, Storage, Handling, and Administration of Enteral Nutrition



Source: Boullata J et al. *Journal of Parental and Enteral Nutrition* 2009;33(2):122-167.

E. Liquid Vs. Powdered 液体相比粉剂

- FDA recommends that when nutritionally appropriate sterile liquid formulas are available, powdered products should be replaced due to sterility issues. FDA建议当有营养适宜的无菌液体配方可用时，由于无菌问题，粉状产品应该被更换。



Source: Boullata J et al. *Journal of Parental and Enteral Nutrition* 2009;33(2):122-167.

E. Liquid Vs. Powdered 液体相比粉剂

- ❑ Reduced bacterial contamination
- ❑ Longer hang time
- ❑ Other reasons (for ONS)
 - Patient intolerant to lactose in powder
 - Patient inability to tolerate solid foods (e.g. inflammatory bowel disease, oesophageal stricture, neck/GI tumor on radiotherapy)
 - Ready-to-drink liquid ONS is nutritionally complete whereas powdered ONS is not
 - Reduced waste during reconstitution/mixing
 - Patient with renal impairment. Powdered ONS has high potassium that may cause hyperkalemia
 - Patient with diabetes. Powdered ONS has high sugar and CHO

F. Liquid FSMP Use – Recommendation/Guideline 特医液体产品应用-建议及指南

- **ONS** first choice of use over **EN** for the malnourished or at risk of malnourished
 - ONS less invasive and more cost effective
 - ONS has antibacterial properties from saliva
- **When** – within 24-48 hours (4-6 hr in burn patients) in hospitalized patients
- **How**
 - ONS \geq 500-600 kcal/day for adults and 600-800 kcal/day in primary care in order to be clinically beneficial; typically administered at twice a day for acute conditions between meals
 - EN >80% energy goal (\leq 65%-70% in obese) in high risk malnourished critically ill patients
- **What**
 - Liquid, sterile formulas be used in preference to powdered, reconstituted
 - Standard formula in initiation and suitable in most cases

Source: ASPEN, The Academy (ADA), SCCM, Canadian Clinical Guideline Group, etc.

G. Select Products – Liquid ONS (Standard Liquid) 常用产品 - 标准型口服营养补充液

□ Ensure Plus

- Abbott
- 1.5 kcal/ml, 330kcal and 13.8 g protein per 220ml bottle
- Ready-to-drink, gluten-free
- 10 flavours – neutral, banana, chocolate, coffee, fruits of the forest, orange, peach, raspberry, strawberry and vanilla



□ Resource Energy

- Nestlé
- 1.5 kcal/ml, 300kcal and 11.2 g protein per 200ml bottle
- Ready-to-drink, gluten-free
- 6 flavours – apicot, banana, chocolate, coffee, strawberry/raspberry and vanilla



G. Select Products – Liquid EN (Standard Formula) 常用产品-标准配方液体肠内营养

□ NUTREN 1.0

- Nestlé
- 1.5 kcal/ml, 228kcal and 10 g protein per 237ml bottle



E. FNH/WNRC/UBC (不列颠哥伦比亚大学)简介

- ❑ 1908 established
- ❑ Among the top ranked in Canada
- ❑ Currently 63,000 students (10,500 postgraduates), 5,500 academic staff, 10,000 administrative staff
- ❑ Notables – 4 Canadian prime ministers, 7 Nobel laureates, 68 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. Contact Info 联系信息



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