

The Canadian Regulatory Environment for Natural Health Product

加拿大天然健康品法規剖析

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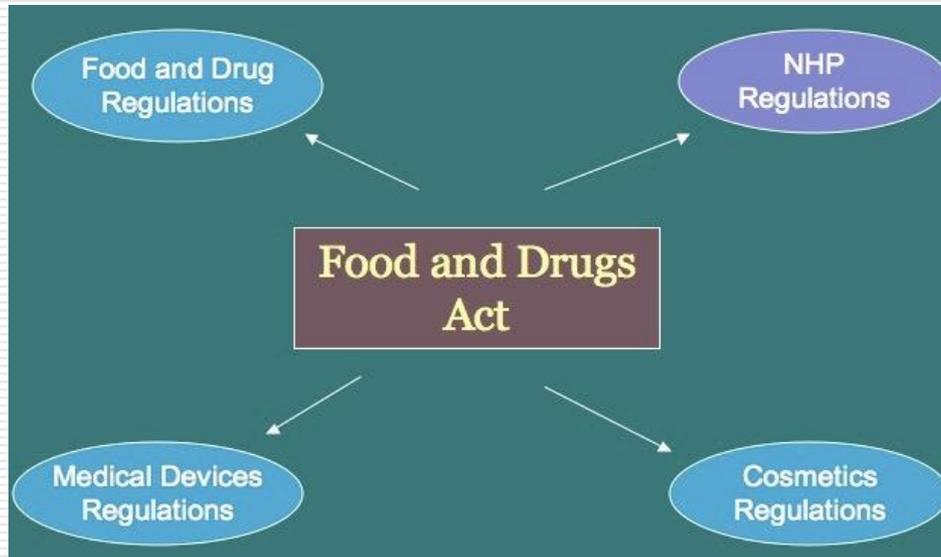
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Presentation Outline 讲座提要

- A. Canadian NHP Regulations 加拿大天然健康品法规
- B. Opportunity 机遇
- C. Case Studies 案例
- D. Wellgenex Brief Introduction 公司简介
- E. Q & A 问答

A. Regulations - Overview 法规简述



- Used to be either food or drug before 2004
- NHP regulations introduced on 01/01/2004 by Health Canada
- Regulated as subset of drugs. Pre-market approval required.
- NHP regulations: **Product licensing, site licensing/GMP, clinical trials, labeling, adverse reaction reporting**

A. Regulations - NHP Definition 天然健康品定义

Substance:

1. A plant, an alga, a bacterium, a fungus or a non-human animal material
2. An extract or isolate of the above
3. Vitamins (selected)
4. Amino acids
5. Essential fatty acids
6. Synthetic duplicates of any of 2 to 5
7. Minerals
8. Probiotics

Permitted claims:

1. Therapeutic - diagnosis, treatment, mitigation, or prevention (except Schedule A diseases)
2. Risk reduction
3. Structure/function

A. Regulations - Product Licensing (PL) 产品注册认证

- Types of product license application (PLA)
 - Compendial (i.e. monograph)
 - Traditional claim (e.g. TCM/CM)
 - Non-traditional claim
 - Homeopathic
 - Transitional DIN
- Required supporting evidence in PLA
 - Efficacy
 - Safety
 - Quality
- PL open to foreign applicants with Canadian representatives
- PL issued as Natural Product Number (NPN)

A. Regulations - GMP & Site Licensing (SL) 场地认证

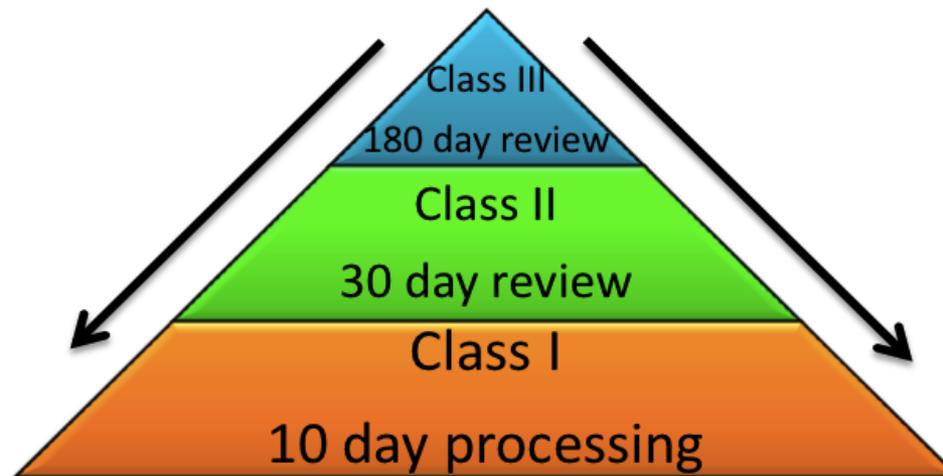
- GMP required to ensure product safety and quality. SL required for all manufacturers, packagers, labelers and importers in Canada
- Foreign sites
 - Foreign site must meet Canadian GMP requirements
 - Evidence required for SL application (one of the following):
 - Audit report
 - Quality Assurance Report (QAR)
 - Drug establishment license (DEL)
 - Certificate of Compliance (COC)
 - GMP Certificate
 - Others
 - Asia countries with qualified authority for GMP certificate – Taiwan, Indonesia, Japan, Korea, Malaysia, Singapore
 - Countries with Mutual Recognition Agreement (MRA) for COC - The European Community, Switzerland, Australia

A. Regulations - Clinical Trials 临床试验

- Clinical trial not mandatory for PLA
- NHP clinical trials (Phase I-III) allowed for:
 - New condition(s) of use
 - Additional evidence to support PL application and approval
 - NHP with no prior history of use in humans
 - Comparative bioavailability studies on two NHP
 - NHP used to treat side effects of a conventional drug
 - NHP used to enhance efficacy of a conventional drug
- Full clinical trial application (CTA) required to be filed with Health Canada to obtain Notice of Authorization (NOA) prior to the commencement of the trial
- Health Canada only authorizes trials to be conducted in Canada

A. Regulations - License Application Timeline

注册认证时间



- PL – 10 to 210 days
 - Class I: NNHPD monographs
 - Class II: Combination of NNHPD monographs
 - Class III: Others
- SL - 45 days to 6 months

A. Regulations - License Application Cost 注册认证费用

- Currently no application fees
- Cost recovery scheme proposed (table below) pending implementation

Application Type	Fee	Timeline (in days)
Compendial PL	\$1,500	60
Compendial-like PL	\$1,700	150
Non-compendial (single ingredient) PL	\$1,810	150
Non-compendial (multi-ingredient) PL	\$3,610	150
SL	\$2,110	60

A. Regulations – Summary 法规总结

- Regulated by NHP Regulations as a subset of drugs
- Require pre-market approval
- Structure-function, Risk-reduction, and Treatment or Therapy claims are permitted
- Specific labeling requirements
- GMP compliance required
- Site Licenses required
- Approval required from NHPD for clinical trials
- Mandatory Adverse Reaction Reporting

B. Opportunity 机遇

- Health Canada product license opened to foreign applicants
- Allowable direct and strong claims (therapeutic, risk reduction, structure/function) for products
 - TCM/CM modernization and internationalization
 - Botanical medicine and phytomedicine
 - Nutritional and dietary supplements
 - Clinical nutrition and medicinal food
- Approved in Canada and/or made-in Canada products better perceived by consumers
- Greater mainstream market access domestically and globally

C. Case Studies - Alive Vitamins, Canada 案例

The screenshot shows the Health Canada website interface. At the top, there are logos for Health Canada and Santé Canada, along with the word 'Canada'. Below this is a banner image featuring a diverse group of people and a red maple leaf. The 'Health Canada' logo and website URL 'www.hc-sc.gc.ca' are centered on the banner. A navigation bar contains links for 'Français', 'Home', 'Contact us', 'Help', 'Search', and 'canada.gc.ca'. Below the navigation bar is a breadcrumb trail: 'Home > Drugs and Health Products > Natural Health Products > Licensed Natural Health Products Database'. The main heading is 'Drugs and Health Products', with a 'Print' icon and 'Text Size: S M L XL Help' options. A 'Product Information' section contains three buttons: 'User Guide', 'Terminology Guide', and 'Compendium of Monographs'. Below this is a 'New Search' link and a table of product details.

Natural Product Number:	80002123
Current Status:	Active
Brand Name(s):	Glucosamine Sulfate 500 Mg Osteoarthritic Joint Pain Relief
Name of Licensee:	Alive Vitamins
Dosage Form:	Capsule
Recommended Route of Administration:	Oral

C. Case Studies – Nature’s Way/Enzymatic Therapy, United States 案例

Health Canada Santé Canada

Canada

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Home > Drugs and Health Products > Natural Health Products > Licensed Natural Health Products Database

Drugs and Health Products

[Print](#) | [Text Size: S M L XL Help](#)

Product Information

User Guide	Terminology Guide	Compendium of Monographs
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[New Search](#)

Natural Product Number (NPN):	80054995
Current Status:	Active
Brand Name(s):	Thisilyn Cleanse With 6-Fiber Blend
Licence Holder:	Nature's Way of Canada Ltd/ Enzymatic Therapy (Canada) Inc
Dosage Form:	Capsule
Recommended Route of Administration:	Oral

C. Case Studies - Foods For Beauty, Hong Kong 案例

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Drugs and Health Products

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Product Information

[User Guide](#) | [Terminology Guide](#) | [Compendium of Monographs](#)

[New Search](#)

Natural Product Number: 80011513
Current Status: Active
Brand Name(s): Skin Vitamins And Minerals
Name of Licensee: Foods for Beauty Enterprise Limited
Dosage Form: Tablet
Recommended Route of Administration: Oral

Recommended Dose:

Sub Population (Sub Pop.)					Amount				Frequency (Freq.)			
Sub Pop.	Age	Min.	Max.	UoM* Age	Quantity (Qty)	Min.	Max.	UoM* Qty	Freq.	Min.	Max.	UoM* Freq.
Adults					1.0			tablet	3			daily

* UoM: Unit of Measure

Recommended Use or Purpose:
 Helps to maintain healthy skin. Helps in tissue formation. Helps to produce and repair connective tissue. Helps to maintain eyesight, skin, membranes and immune function. A factor for the maintenance of good health. Provides antioxidants for maintenance of good health. Helps the body to metabolize carbohydrates, fats and proteins.

C. Case Studies – Sichuan Huaxi Pharma, China 案例



Health Canada Santé Canada Canada


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Home > Drugs and Health Products > Natural Health Products > Licensed Natural Health Products Database

Drugs and Health Products

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Product Information

User Guide	Terminology Guide	Compendium of Monographs
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[New Search](#)

Natural Product Number (NPN):	80037542
Current Status:	Active
Brand Name(s):	Lemai Keli
Licence Holder:	Sichuan Chuanda West China Pharmaceutical Co., Ltd.
Dosage Form:	Granules
Recommended Route of Administration:	Oral

C. Case Studies – Foreign Site (China) 案例



Site Licence Number: Numéro de la licence:	300493	Expiry: Expiration:	January 25, 2016
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Foreign Company Name: Nom de l'entreprise étrangère:	Sichuan Chuanda West China Pharmaceutical Co., Ltd.		
Address: Adresse:	26 Gaopeng Street, Hi-Tech Development Zone Chengdu 610041 China		
Activities / Activités	Authorized Activities / Activités autorisées	Specific Authorization / Autorisation spécifique	
		Sterile Dosage Form / Forme posologique stérile	Homeopathic Medicine / Remède homéopathique
Manufacturing/Fabrication:	YES/OUI	NO/NON	NO/NON
Packaging/Emballage:	YES/OUI	NO/NON	NO/NON
Labelling/Étiquetage:	YES/OUI	NO/NON	NO/NON

C. Case Studies - Foreign Site (Hong Kong) 案例



SITE LICENCE

Site Licence Number:
Numéro de la licence :
300493

**LICENCE
D'EXPLOITATION**

Foreign Site Annex/Annexe des sites étrangers

The following sites are considered to be in compliance with GMP requirements outlined in PART 3 of the Natural Health Products Regulations.

Les sites suivants sont considérés conforme avec les normes des bonnes pratiques de fabrication tel que stipulé dans la partie 3 du Règlement sur les produits de santé naturels.

Foreign Company Name: Nom de la compagnie étrangère :		Phartech (Hong Kong) Limited	
Building Name: Nom du bâtiment :		Phartech (Hong Kong) Limited	
Address: Adresse :	Unit 1C, 6/F, Cheung Fung Industrial Bldg, 23-39 Pak Tim Par St.	City: Ville :	Tsuen Wan
		Province/State/État:	Hong Kong
Postal Code: Code postal :	N/A	Country: Pays :	P. R. of China
Activities/ Activités	Authorized Activities/ Activités autorisées	Specific Authorization/ Autorisation spécifique	
		Sterile Dosage Form/ Forme posologique stérile	Homeopathic Medicine/ Remède homéopathe
Manufacturing/Fabrication	YES/OUI	NO/NON	NO/NON
Packaging/Emballage	YES/OUI	NO/NON	NO/NON
Labelling/Étiquetage	YES/OUI	NO/NON	NO/NON

C. Case Studies - Clinical Trial NOA (Wellgenex) 案例



D. Wellgenex 公司简介

□ Corporate highlight:

- A Canadian professional firm focusing on life sciences, clinical nutrition and natural health in North America (Canada, US) and Asia Pacific (China)
- Experts with extensive expertise in academia, industry and government bridging the gap between science and business
- Currently serving clients from Canada, US, China, India, Hong Kong, Taiwan, Japan, Singapore, Korea, Switzerland, Germany, etc.

□ Area of specialty:

- Scientific / regulatory affairs
- Product development / commercialization
- New market entry / strategic alliance

Wellgenex是加拿大一家专注于生命科学包括临床营养天然健康药品的专业服务公司

- 科学法规事务, 认证与注册
- 产品研发, 商业化及临床试验
- 新市场拓展, 战略伙伴建立

Helping you create product excellence and connect to market success

E. Q & A 问答

谢谢!



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