Health Canada Santé Canada

Canada

Regulation of Natural Health Products in Canada

Presentation at Dietary Supplement Public Meeting

Manon Bombardier
Director General, Natural and Non-prescription Health Products
Health Canada

May 16, 2019

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

1. Regulatory Context

- *Natural Health Products Regulations* (NHPR)
- What can be included in Natural Health Products (NHPs)?
  - Approach to Synthetic Duplicates
  - Approach to Probiotics

2. Pre-Market Review

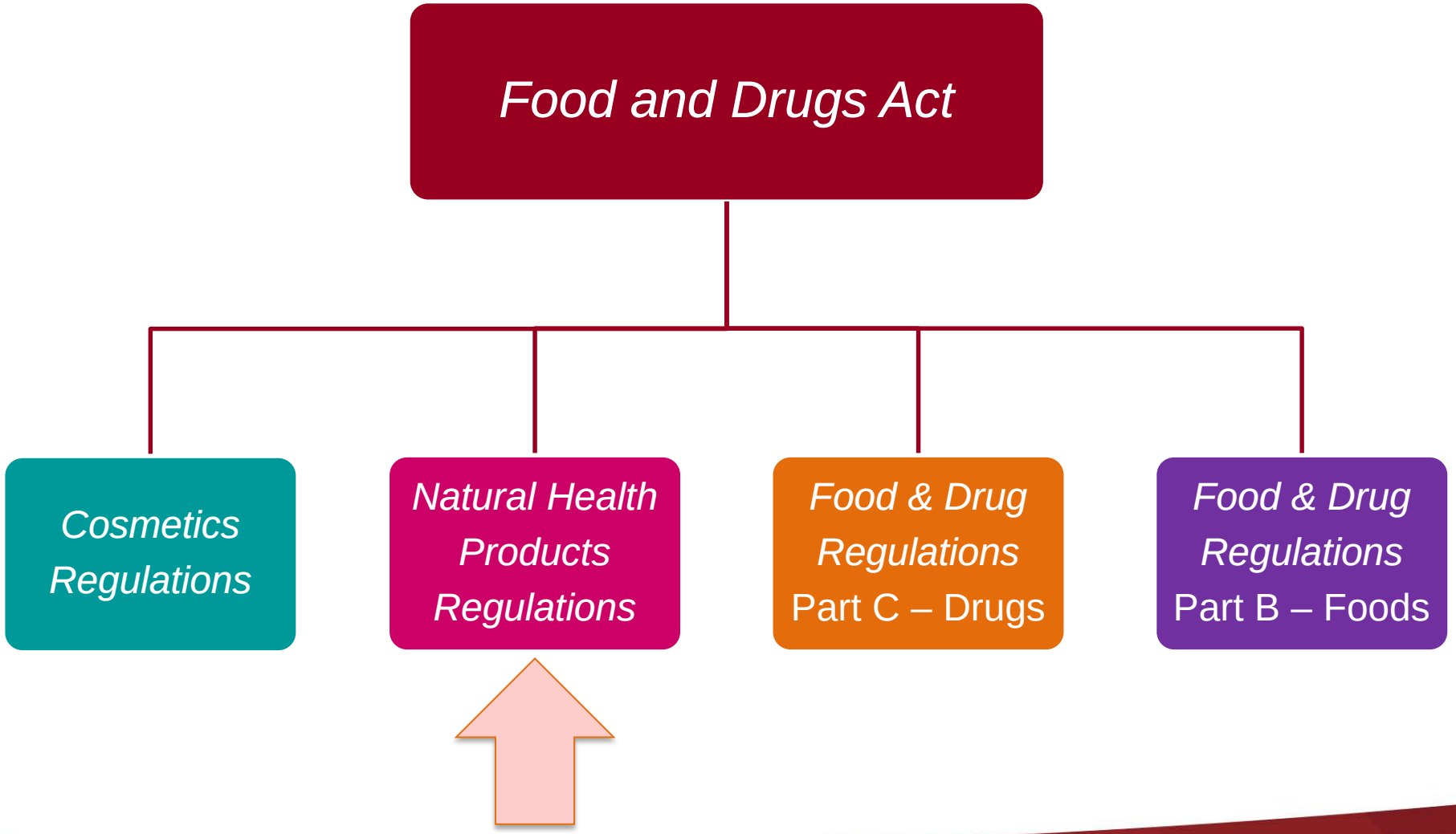
- Product pathways
- Approach to Safety and Efficacy and Experience to Date
- Approach to Quality and Experience to Date
- Processing Overview

3. Post-Market Activities

- Reactive Approach
- Proactive Approach

4. Current Regulatory Modernization Efforts

Regulatory Context



Natural Health Products Regulations (NHPR)

- All NHPs sold in Canada are subject to the NHPR, which came into effect in 2004
- Result from extensive consultation with broad range of stakeholders.
- Take into account concerns about NHP availability and safety, as well as the House of Commons Standing Committee on Health's 53 recommendations on the regulation of NHPs in Canada
- Purpose is to balance access to NHPs with the need to ensure appropriate standards are in place for:
  - Safety;
  - Efficacy; and
  - Quality

Scope of NHPs

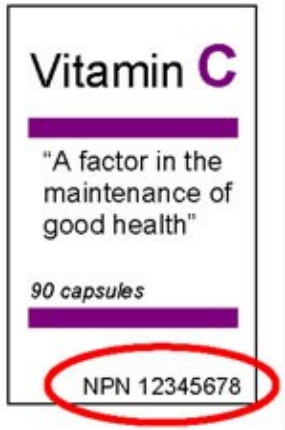
In Canada, “natural health product” refers to a range of health products including:

- Vitamin and mineral supplements
- Homeopathic medicines
- Plant and herbal remedies
- Traditional medicines
- Probiotics
- Certain personal care products

A 2010 survey showed that 73% of Canadians regularly take NHPs.

A 2016 survey showed that Canadians have low perceived knowledge of safety and effectiveness of NHPs (19%) and generally feel uninformed when purchasing these products (33-58%)

Authorized NHPs bear either a natural product number (NPN) or homeopathic medicine number (DIN-HM) on their labels

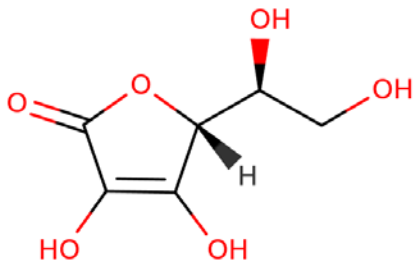


There are currently over 150,000 NHPs authorized for sale in Canada

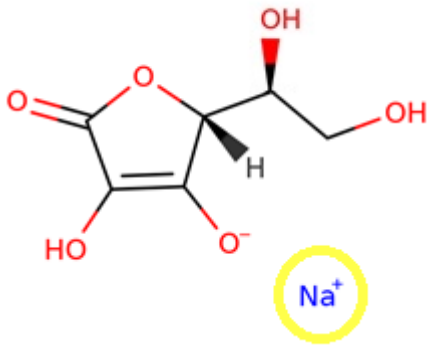
Approach to Synthetic Duplicates

- As an example, the NHPR allows for an extract or isolate of a plant, alga, a bacterium, fungus or a non-human animal material

- The activity of the synthetic substance should be identical to that of the naturally isolated substance



Vitamin C (as ascorbic acid) commonly found in citrus fruits and many vegetables



Sodium ascorbate (synthetic), provides ascorbic acid

Approach to Probiotics

- Generally regarded as live microorganisms that provide a health benefit.
- Health Canada's monograph[1] for probiotics includes:

  - **General Health Claim** for all listed species:
    - Source of Probiotics
  - **General Health Claims** for **almost all** listed species:
    - Helps support intestinal/gastrointestinal health
    - Could promote a favorable gut flora
  - **Other strain specific claims**:
    - Acute infectious diarrhea (*Lactobacillus rhamnosus* GG)
    - Antibiotic associated diarrhea (L. rhamnosus GG, S. boulardii/cerevisiae (all))

[1] http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=probio&lang=eng

Pre-Market Review: Product Pathways

- **Modern NHPs** (*e.g.,* vitamins, fish oils) – evidence is stratified by risk and decision informed by a variety of sources including clinical trials, information from other regulatory agencies and scientific literature

- **Traditional Medicines** (*e.g.,* Traditional Chinese Medicine) – based within a defined healing paradigm and supported by references to specified pharmacopoeia or other texts deemed acceptable by Health Canada. Safety considers the scientific literature as well

- **Homeopathic Products** (*e.g.,* nosodes) – evidence must come from an accepted homeopathic reference (homeopathic pharmacopoeia), proving (homeopathic testing), or clinical trial data

Approach to Safety and Efficacy

Class I 60 calendar days	• Products that comply with all parameters of an **individual monograph** • Risk-based review
Class II 90 calendar days	• Products fully supported by a **combination of monographs** • Full review

Class III
210 calendar days
	• Other Products
	  • One or more non-monographed ingredients[1], and/or
	  • Monographed ingredients but outside monograph parameters (e.g. higher dose, different source, unacceptable claim, etc.)
	  • Full scientific review

- Issues with attestation model identified in early 2017 led to adjustment in pre-market review
- The Natural Health Products Ingredients Database (NHPID)[1] is an electronic repository of monographs, information on medicinal and non-medicinal ingredients in NHPs, and ingredients classification for selection in an electronic Product Licence Applications (e-PLA) submission

[1] http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do?lang=eng

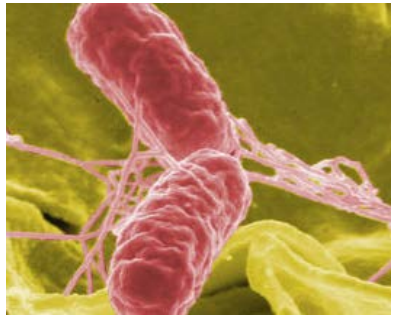
Approach to Quality

Identity:

- Physical description; and
- Chemical Identity for the respective medicinal ingredient(s)

Purity/Contamination:

- Microbial;
- Chemical; and
- Other (Pesticides, Solvent residues, etc.)



Quantity/Potency:

- Amount of each medicinal ingredient

Approach to Quality - Experience to Date

- Review of 1192 site licence (SL) applications identified issues with the current attestation model:
  - Specifications (52%)
  - Stability (35%)
  - Quality Assurance (13%)

- Proactive inspections at 46 NHP sites (~6%) conducted over past 3 years[1] identified issues ranging in severity found at all facilities, notably:
  - Specifications: unavailable or incomplete
  - Stability: no data, scientific rationale or program available to establish a product's shelf life
  - Quality Assurance: products not properly assessed against their specifications with partial or no testing

- Paper-based audits of 35 licensed sites (~4%) currently underway, focusing on key areas of concern

- Results will inform adjustments to pre-market quality review approach (Fall 2019)

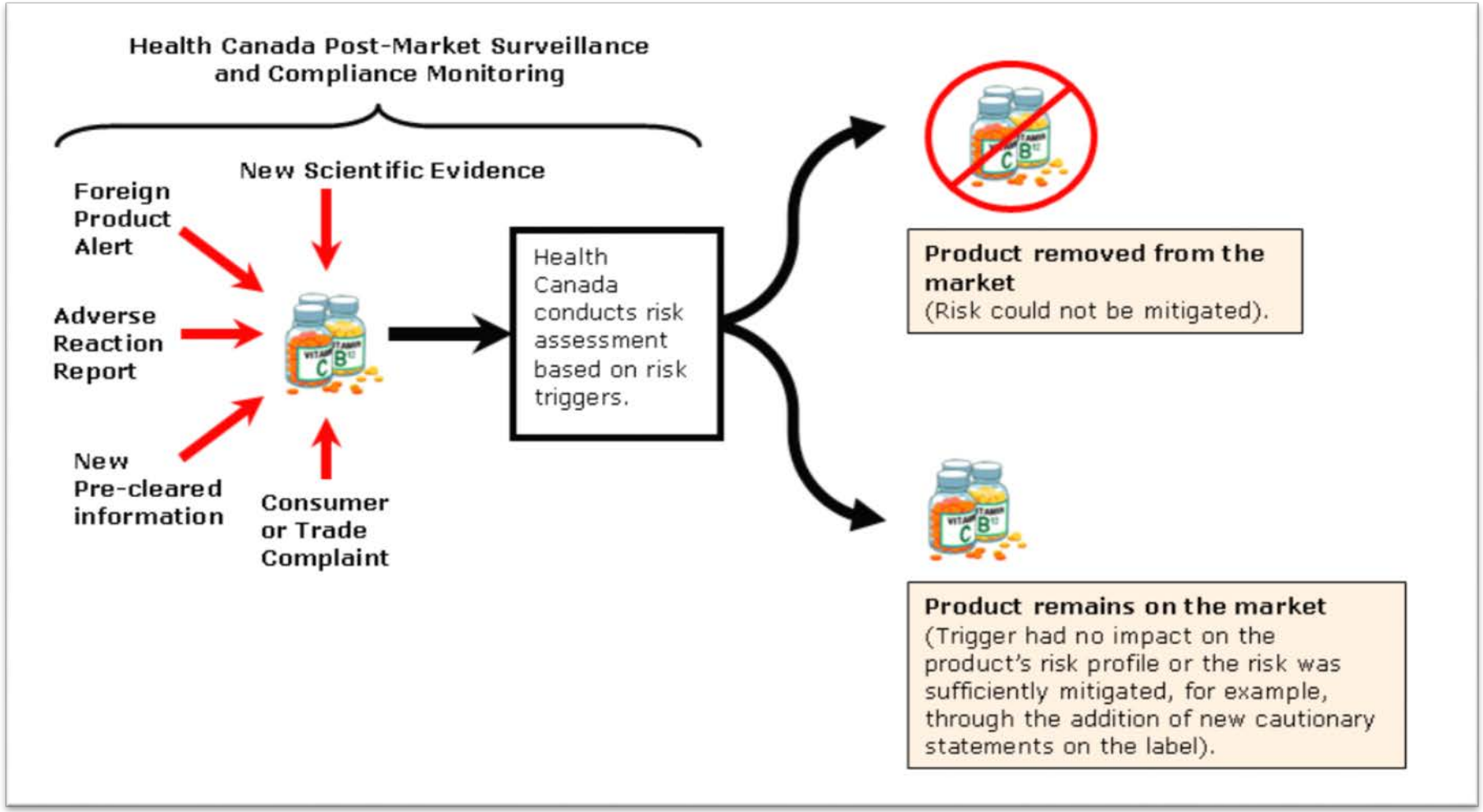
[1]2017 Report on Compliance Monitoring: Natural health products at https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/compliance-monitoring-reports/2017-reporting-compliance-monitoring-natural-health-products.html

Processing Applications

- NHP Management of Applications Policy[1] updated in April 2019.
- Updates intended to achieve better outcomes for the health and safety of Canadians by ensuring that authorized NHPs meet all regulatory requirements. Changes also
  - Reflect evolving regulatory and market context
  - Align with current practice as well as with changes in the web-based application systems, i.e.
    - Attainable performance standards
    - Improved predictability of licensing application review outcomes through
      - Clear and precise application criteria; and automatic refusals when not met
      - No more paper applications
      - More efficient and comprehensive correspondence
      - No unsolicited changes

[1]NHP Management of Applications Policy at https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-health-products/legislation-guidelines/guidance-documents/management-product-licence-applications-attestations.html

Post-Market Activities : Reactive



Post-Market Activities : Proactive Monitoring

- Legislative prohibition against false, misleading or deceptive

  s.9 of the *Food and Drugs Act* :

  "*No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety*"

- Proactive monitoring of marketed NHPs in development:
  - Proactively monitor products on the Canadian market to identify possible non compliance issues; and
  - Take action as appropriate

- Health Canada also works in collaboration with independent advertising preclearance agencies to educate and promote compliance on advertising

Current Modernization Efforts
Regulation of NHPs, Non-Prescription Drugs and Cosmetics

Oversight proportional to risk

Similar evidence for similar claims

- Product Categorization
- Product Claims and Evidence

Informed consumer choice

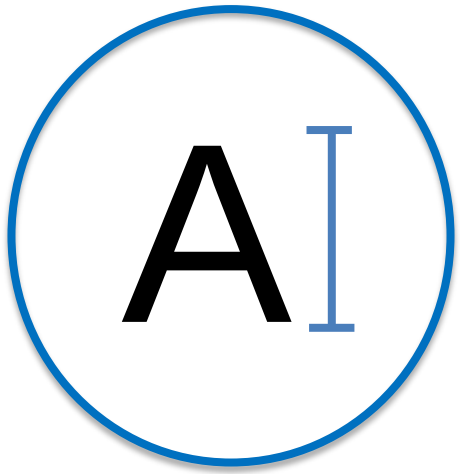
- Improved product labelling

Risk-based post-market oversight

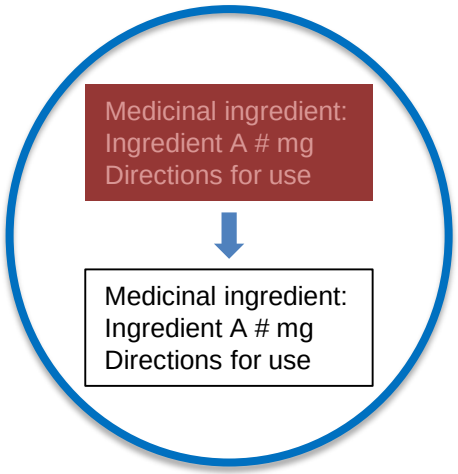
- Compliance Monitoring & Verification
- Site Licensing
- Quality Standard
- Vigilance

Proposal: Improved Labelling of NHPs

Requirements – Updates to the NHPR:



Minimum font size



Maximum contrast

Standardization

Product Facts Table

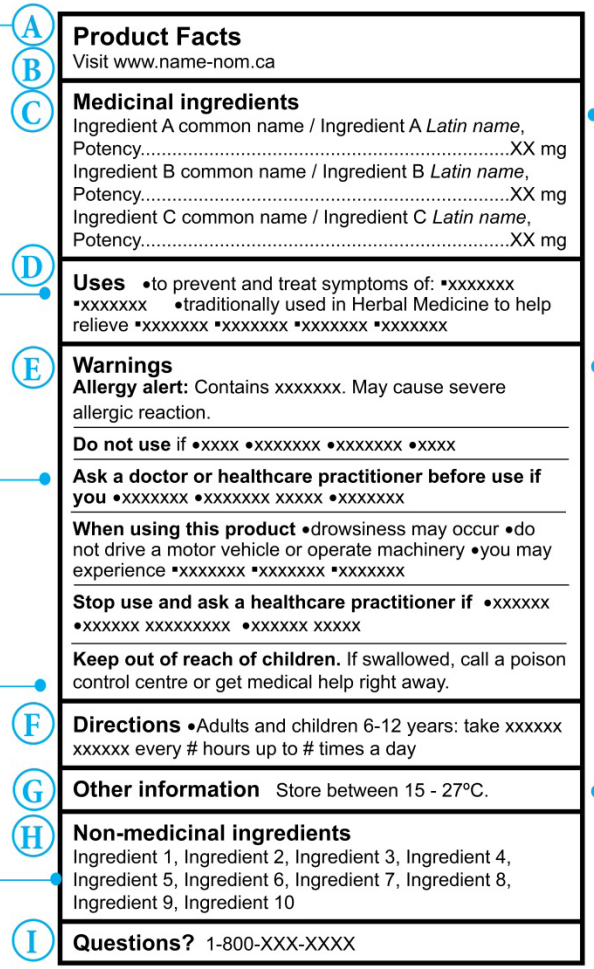
Title:
8 pt sans serif font bold

Headings:
7 pt sans serif font bold

Subheadings:
6 pt sans serif font bold

Body text:
6 pt sans serif font

Weight of rules: 1.5pt



Quantitative list of product's medicinal ingredients.

Warnings to be included in prescribed order:

- For external/rectal/vaginal use only
- Reye's syndrome
- Allergy alert
- Flammability warning
- Choking warning
- Alcohol/liver/stomach bleeding warning
- Sore throat warning
- Dosage warning
- Sexually Transmitted Diseases (STD) alert
- Do not use
- Ask a doctor or healthcare practioner before use if you
- When using this product
- Stop use and ask healthcare practitioner if
- Other warnings
- Keep out of reach of children

Includes storage instructions, special instructions (e.g. for disposal), or nutritional information.

QUESTIONS?