

# Proposed Fees for Natural Health Products

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# Agenda

Topic
Overview of the Fee Proposal
NHP Product Licence Fees
NHP Site Licence Fees
Mystery Novel Class III Applications
What We Don't Know
Industry Concerns

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# Overview of the Proposal

- Published on May 12, 2023
  - ❖ Consultation open for 75 days – **SUBMIT COMMENTS**
  - ❖ Target implementation date: **April 1, 2025**
- Introduce proposed fees for:
  1. NHP Product Licences
  2. NHP Site Licences
  3. Annual Right to Sell
- Small Business Mitigation



# NHP Product Licence Fees

Fee line/category	Proposed fee amount (2025) (\$ CAD)	Existing performance standard (calendar days)	Proposed performance standard (calendar days)
Class I application or amendment	\$1,124	60	60 to review application/amendment
Class II application or amendment	\$2,761	90	120 to review application/amendment
Class III application or amendment	\$7,209	210	210 to review application/amendment
Class III novel application	\$58,332	210 (if treated as a Class III)	300 to review application
Class III novel safety and efficacy amendment	\$23,333	210 (if treated as a Class III)	210 to review amendment
Class III novel quality amendment	\$8,750	210 (if treated as a Class III)	210 to review amendment

# NHP Site Licence Fees

Fee line/category	Proposed fee amount (2025) (\$ CAD)	Existing performance standard (calendar days)	Proposed performance standard (calendar days)
SL application or amendment	\$4,784	30 to 90	180 to review application/amendment
Annual SL – manufacturing – sterile dosage form	\$40,071	30 to 90 (for renewals)	90 to review licence renewal application or confirm licence information
Annual SL – manufacturing – non-sterile dosage form	\$23,071		
Annual SL - importation	\$20,035		
Annual SL - packaging	\$7,650		
Annual SL - labelling	\$6,921		

# Mystery Novel Class III Application = \$58,332

*A product with novel active ingredients, a novel combination of active ingredients, a novel use or purpose, or a novel physical form*

- What is “novel”? Does the fee only apply to the first application?
- Existing Class III PLAs at risk of being reclassified as “Novel”
- HC estimates 1% but questionable data and no clarity

# What We Don't Know



- True definition and impact of mystery novel class III
- 1% estimate vs 1% cap? 1% of what?
- Fees on products in queue vs new application?
- Fees on application vs success?
- Will approach to IRN responses change?
- Small Business Mitigation on Sub vs Global Operations?  
Will ISCs be considered employees for calculation?

# Industry Concerns

- Costs based on questionable assessments
  1. High costs for all classes
  2. Operational inefficiencies
  3. Priced-in COVID costs
  4. Mystery Novel Class III – the unknown and creep
  5. Paying for a broken system Health Canada plans to change
  6. Prospective vs. retrospective costs (i.e. Quality Review)
- Duplicate taxing (Fees + GST/HST)
- No Independent and Industry Trusted Appeal
- Unfair Competition Re Non-Compliant Products





# Questions?

# Who to contact

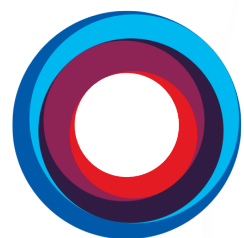


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