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# Engagement on Red Tape Reduction Initiatives for Natural Health Products

**Stakeholder Meeting**

February 10, 2026

# Session overview

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Overview of red tape reduction initiatives for natural health products (NHPs)

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## Reducing red tape for NHPs

On September 8, 2025, the Government published the [Health Canada and the Public Health Agency of Canada's report on red tape reduction](#) committing to:

*“...introduce a **simple registration process for certain NHPs and NPDs**, along with flexible risk-based monitoring for all NHPs and NPDs. The department plans to amend the regulations for NHPs by making labelling requirements more flexible and reducing authorization requirements in areas where oversight is more appropriate after the product is authorized.”*

# Overview

**What:** Address one-size-fits-all approach to regulating NHPs and labelling implementation concerns

**Why:**

- Increased flexibility
- Proportionate oversight
- Expedited pathways to market and reduced burden



## Simple registration process for certain products

**What:** NHPs with higher certainty (e.g., based on a monograph)

**Why:**

- Proportionate oversight
- Enable faster market access
- Reduce regulatory & administrative burden
- Create a sustainable regulatory program



## Prioritizing NHPs that benefit Canada

**What:** NHPs that are sold or made in Canada

**Why:**

- Focus public resources on products that benefit people in Canada



## Simplified labelling requirements

**What:** All NHPs

**Why:**

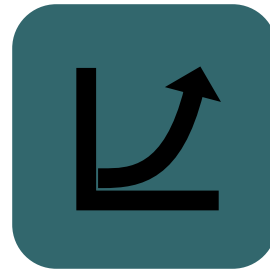
- Facilitate implementation for industry while maintaining consumer outcomes by prioritizing key information on labels
- Incorporation of outcome-based language, where appropriate, to offer flexibility and support innovation

## Policy objectives

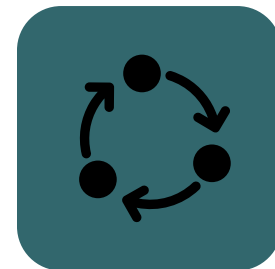
Proposed changes will aim to reduce overall burden, while maintaining consumers' health and safety. Specifically, this would be achieved by:



Aligning level of oversight for NHPs with certainty and reducing administrative requirements



Focusing program resources where needed to support the Canadian economy



Incorporating modern tools to respond to emerging health risks and adapt to new evidence and advancing technology



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# Red Tape Reduction: NHP Policy and Operational Changes

# NHP policy and operational initiatives

- Health Canada has committed to improving processes through clearer submission pathways and more flexible labelling options
- Clear guidance to support stakeholders in their product application
  - Publication of the NHP Monograph Combination Guide (November 2025)
  - Updates to NHP monographs (ongoing) and development of new monographs (e.g., prebiotic monograph under consultation from February 2 to 20, 2026)
  - Development of guidance on Brand Names for NHPs (draft shared January 2026)
- Labelling flexibility to support the implementation of the new NHP labelling regulations and to align NHPs and NPDs with US FDA labelling flexibilities for OTC drugs
  - Publication of List of Interchangeable Terms (November 2025)

## New GC forms implemented in 2025

### **New Company Registration Form** *(for first-time applicants)*

**Launch:** July 9, 2025

**Purpose:** Standardizes the process for requesting and issuing a unique company code

**Volume:** 403

**Impact:** Faster and simpler onboarding of new companies with significantly fewer back and forth emails

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### **NHP Ingredient Database Request Form**

**Launch:** July 11, 2025

**Purpose:** Replaces the defunct NHPID Issue Form (.pdf) and provides a guided process for adding or modifying ingredients in the NHPID

**Volume:** 140

**Impact:** Simpler request process with fewer back and forth emails

## New GC forms implemented in 2025 (cont'd)

### **NHP Application Withdrawal Request Form**

**Launch:** October 27, 2025

**Purpose:** Standardizes and automates the withdrawal process across all application stages

**Volume:** 89 (representing 110 submissions)

**Impact:** Faster and simpler process; able to include multiple PLAs; up to 40% less NNHPD time required

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### **NHP Discontinuation Request Form**

**Launch:** October 27, 2025

**Purpose:** Standardizes and automates the product licence discontinuation process

**Volume:** 63 (representing 1,464 NPNs)

**Impact:** Faster and simpler process; able to include multiple NPNs; approximately 60% less NNHPD time required; leveraged the new automated process to discontinue over 1,400 backlogged discontinuations (a savings of approximately 10 weeks of work)

# Workload Management

## Updated Product Licence Application (PLA) and Amendment & Notification (ANF) Forms

**Launch:** December 15, 2025

**Purpose:** Integrates the expanded workload management eligibility criteria and applies them to all submission classes and types

**Volume:** 1,568 submissions received on the updated forms

**Impact:** Eliminates the need for an additional form; streamlines workload by eliminating unnecessary applications, reducing processing time, and focusing NNHPD resources on products that benefit Canadians

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## Two-week PLA Form and ANF Downtime

**Launch:** December 1-15, 2025

**Purpose:** Enable the transition to the updated forms and clear the processing backlog

**Volume:** 430 submissions received from the announcement to end of the downtime period

**Impact:** Cleared the Class I processing queue (over 800); reduced the Class II-III processing queue by approximately 500 submissions; reduced current Class 3 processing time by >50%

## NHP MAP – Wave 2 updates

- January 5, 2026, request for information related to:
  - a) Scope of Class II PLAs
  - b) Refusal of Class II and III PLAs
  - c) Introduction of a pause-the-clock mechanism for Class II and III PLAs
- Updates to the MAP in alignment with RTR
  - Refer to the Appendix
  - If you have not done so yet, share with us any additional suggestions
    - Use the feedback form provided for this session
    - Indicate which of your proposed changes would provide the greatest burden relief

## Opportunity for feedback



Do you have any initial observations or feedback regarding the proposed policy and operational changes?



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# Red Tape Reduction: NHP Regulatory Changes



# Vision for a simple registration pathway

## Pathway based on product certainty

- Higher certainty products would follow the registration pathway
- All other products would follow the existing licensing pathway

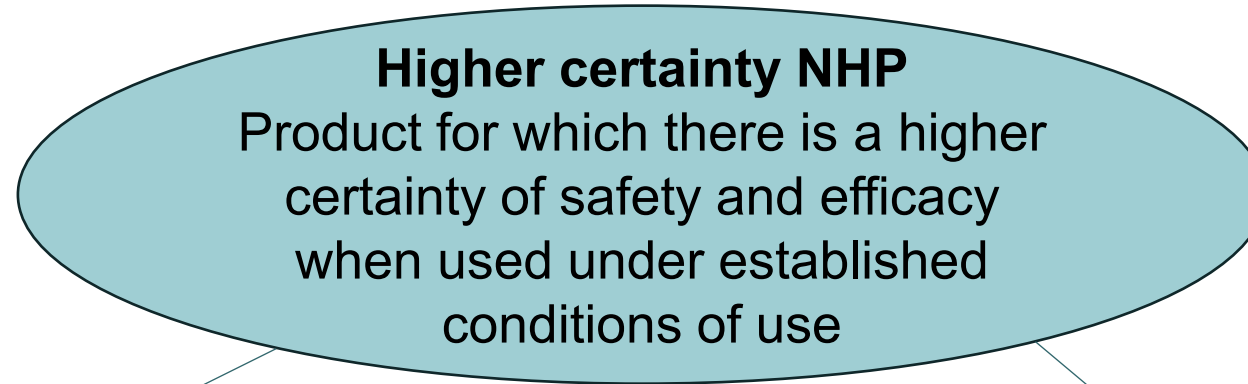
## Key aspects of a simple registration pathway

- Registration is intended to be an administrative process
- No review or authorization by Health Canada before market entry
- Products would remain subject to risk-based post-market compliance monitoring approach
- Registered products would be distinguishable from licenced products for consumers

## Benefits

- Registration would be quicker, with less administrative burden than licensing
- Companies would not need to wait for approval before marketing their products
- Post-registration changes would be less burdensome than current post-licensing requirements

# Scope of products for registration pathway



## Supported by monographs

Monographs serve as precleared safety and efficacy evidence that has been previously reviewed by Health Canada

Monographs are currently used to speed up the pre-market review for products meeting all monograph conditions (Class I)

## Flexible eligibility

Eligible products would be those with monographs included on a list incorporated by reference in the NHPR

Product that fully complies with all parameters of individual ingredient or product monograph (current Class I)

Future consideration: addition of some current Class II products with higher certainty

# Key elements of a registration process

## Registration information

Key information collected to support product identification and post market oversight (e.g., site information)

Declaration that the product complies with all regulatory requirements and monograph parameters

## Record keeping

Maintenance of all records including for information that is not submitted at registration, such as product specifications

Records may be requested by Health Canada within a timeframe established by the Department

## Registration number

Issuance of a registration number upon form submission

Registration number would be used for administrative purposes and to confirm registration

## Product changes

Amendments within monograph parameters would not be required

Post-market changes to registration information would be through notification

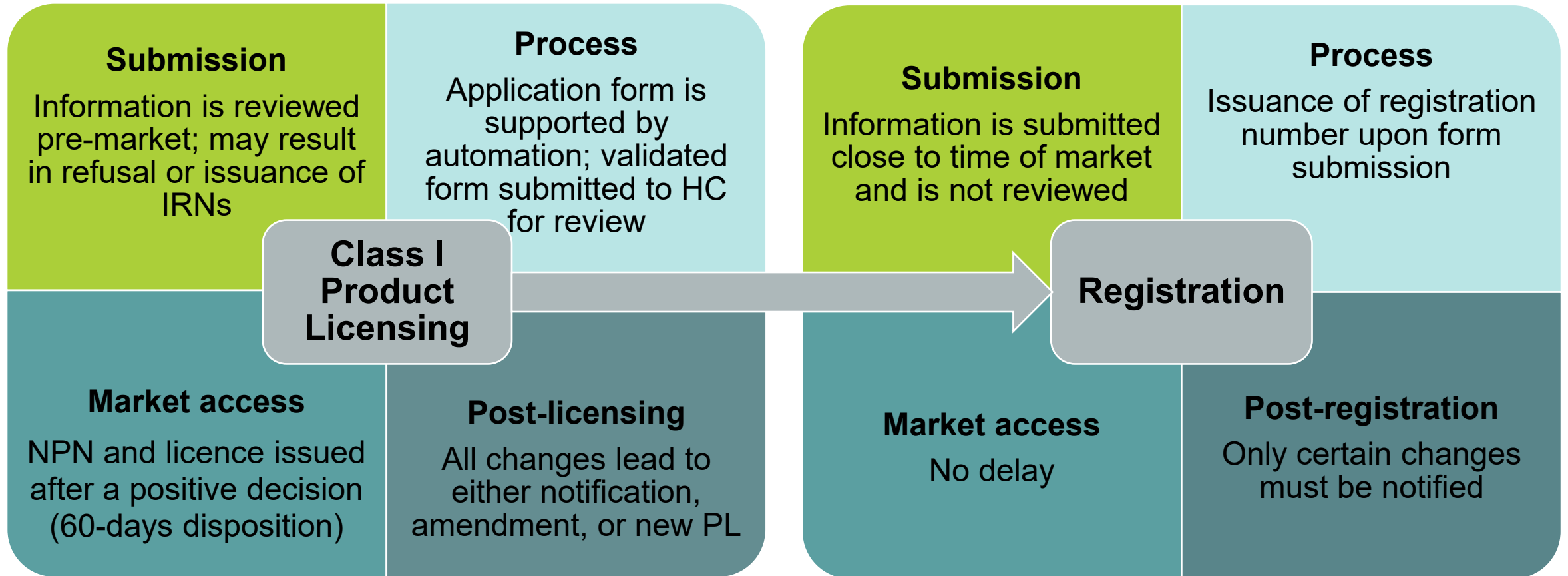
## Post-market authorities

Post-market authorities would be applicable to all NHPs to manage identified risks; amendments would be necessary to certain provisions to capture licensed and registered products

## Managing registration using incorporation by reference

- A list that defines which products are eligible for registration and is maintained by Health Canada would be made part of the NHPR by “incorporation by reference”
- The list would point to the Health Canada monographs that products must follow
- The use of this tool would provide flexibility over time:
  - allow updates as certainty of supporting evidence changes over time (for example, adding new monographs) and in response to an emerging health or safety risk
  - require products to remain compliant with the applicable monographs as they are updated; implementation timelines would be risk-based
- Amendments to the list would follow the process outlined in Health Canada’s Incorporation by Reference Policy

# Moving from licensing to registration for higher certainty NHPs



## What we have heard to date

- In December 2025, the department met with targeted industry associations to gather early feedback on the concept of a registration system
- Participants were asked for input on a series of questions to help inform today's presentation; feedback varied for most topics

### General

- There was overall support for a faster and less burdensome path to market
- Some participants noted that the current licensing model is recognized globally and supports entry to international markets and consumer trust

### Timing of registration

- Some participants saw value in pre-market registration and others preferred a post-market approach

### Numbers for registered products

- Some participants viewed product-specific numbers as important to support supply chain management, recalls and domestic and international recognition
- Others suggested there was no need to label products with specific numbers

## Opportunity for feedback



Do you have any initial observations or feedback regarding the proposed registration process?

# Submission requirements for all NHPs

## Finished product specifications

- Submission of product specifications would not be required for registered products
- Health Canada may request product specifications with a licence application to determine if an NHP is safe and effective when used in accordance with the recommended conditions of use
- Records may be requested by Health Canada and must be provided within a specified timeframe
- All product sponsors and product licence holders would remain responsible for ensuring product quality and establishing product specifications, and maintaining quality information records

## Label text

- Submission of label text would not be required for registered products
- Health Canada may request label text with a licence application to determine if an NHP is safe and effective when used in accordance with the recommended conditions of use
- Label text may be requested by Health Canada and must be provided within a specified timeframe
- All product sponsors and product licence holders would remain responsible for ensuring that product labels meet all regulatory requirements

# Making changes to licensed NHPs

## Amendments and Notifications

- Considering a risk-based approach to allow some post market changes to be submitted as notifications rather than amendments
  - For example, a change of the source material of a medicinal ingredient, when the change does not impact the quantity of the medicinal ingredient and for which the source is published in a Health Canada monograph

## Fundamental changes

- Considering modifying the fundamental change provision to better reflect the unique challenges associated with producing NHPs. For example:
  - Some fundamental changes could be treated as amendments if the evidence for the change is in a Health Canada monograph and does not alter the product's purpose or use; or
  - Industry could decide when to submit a new application versus an amendment; some changes could require informing consumers, such as with a statement like “new formula”

## Opportunity for feedback



Do you have any initial observations or feedback regarding the other proposed regulatory changes?

## Labelling: Context

- Labelling amendments to the Natural Health Products Regulations came into force in June 2025; prior to this, Health Canada heard from industry stakeholders that they are facing challenges implementing the new rules for some products
- In response to the feedback, the Department:
  - Held a series of engagement sessions with stakeholders, which provided a clear understanding of key challenges and perspectives on possible solutions
  - Published a Ministerial Exemption Order, aligning the compliance date for all NHPs to June 21, 2028
- In alignment with the Health Canada and the Public Health Agency of Canada's report on red tape reduction, the department is exploring approaches to reduce burden through simplified requirements and the enhanced use of digital labelling while continuing to support consumer safety

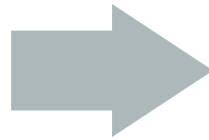
# Labelling: Proposal

## Purpose:

- Simplify requirements
- Increase flexibility
- Increase use of digital labelling

## Expected Outcomes:

- Implementation challenges are alleviated
- Products can be easily compared
- Labels prioritize critical information; improving readability
- Required information remains accessible
- Regulations are adaptable



## Proposed solutions:

- All products would be able to benefit from the same flexibilities for the product facts table (flexibilities are no longer graduated in nature)
- More information could be moved to a digital label or leaflet (e.g., Latin binomial name, extract ratio, certain cautionary information via a list incorporated by reference)
- Guidance is outcome based, technologically neutral, and recommends a variety of ways to meet requirements
  - Flexibilities do not rely on the use of bilingual principal display panel
  - Homeopathic-specific labelling requirements include flexibility

## Labelling: Next steps

- In November 2025 Health Canada met with targeted stakeholders to provide more details on the proposed solutions; some additional feedback was provided, and the following are under consideration:
  - Alternative ways to support consumers' ability to understand health risks associated with NHPs and make informed choices without requiring information to be formatted in a table
  - Collaboration with food allergy experts to review the requirement for food allergy labelling on topical NHPs
  - Review of information that can be made available digitally

## Opportunity for feedback



Do you have any initial observations or feedback regarding the labelling proposal?

# Safety monitoring

## Current state

Required preparation of annual summary reports

## Possible approach

Flexible safety monitoring

### How this could look:

- Replace annual summary report requirement with safety monitoring to detect safety issues
  - Outcome-based requirements provide flexibility to registrants and licence holders throughout the product's lifecycle in the design of risk-based systems and procedures to detect issues
  - Real-world safety information considered in real-time, focusing on the identification of safety issues as they emerge
- Where an issue is identified, the Minister would have the authority to require a focused issue-related report, where warranted.



**Note:** Safety monitoring and issue-related report would be similar to the biocides model

## Opportunity for feedback



Do you have any questions or initial thoughts regarding the proposal for safety monitoring?

# Record retention

## Current approach

Implicit requirements based on annual summary reporting

## Possible approach

Clear retention requirements tailored to risk of NHPs

### How this could look:



Maintenance requirements that arise upon licencing / registration and cease 5 years following discontinuance



Retention of vigilance records for 10 years (or until 5 years following discontinuance, whichever occurs first)



Supports safety monitoring model



Increased alignment with similar product lines (non-prescription drugs, biocides)

## Opportunity for feedback



Do you have any questions or initial thoughts regarding the proposal for record retention?

## Risk-based renewals

**Site licence renewal process  
not commensurate with risk**

**Risk-based renewal  
process with tailored GMP  
evidence requirements**

### **Red Tape Reduction Goal:**

A site licence renewal process that tailors evidence submission requirements based on risk-based factors such as compliance history or licensable activities

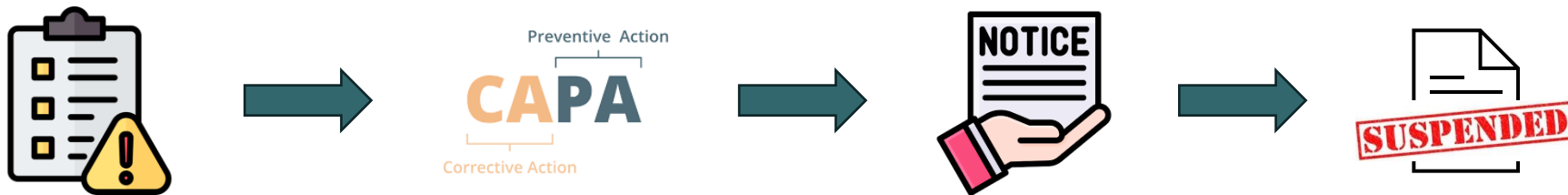
## Modernized suspension framework

Site licence suspension process concurrent with CAPA plan review

CAPA plans reviewed prior to considering escalated enforcement measures (i.e., suspension)

### Red Tape Reduction Goal:

A more agile suspension framework that is separated from the CAPA process



# Regulatory timelines and next steps

Winter – Spring 2026	Fall 2026	Winter- Spring 2027	Spring 2027
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## NHP



- The Department is planning targeted engagement sessions throughout 2026 to discuss the Red Tape Reduction initiatives
- Stakeholders will have the opportunity to provide feedback during the sessions, in writing and at the public CG Part I consultation
- Following this session, stakeholders will be invited to complete a feedback form on the NHP RTR proposals, due by March 13, 2026.

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# Thank You

## Contact:

Natural and Non-prescription Health Products Directorate: [nnhpd.consultation-dpsnso@hc-sc.gc.ca](mailto:nnhpd.consultation-dpsnso@hc-sc.gc.ca)

## General form issues:

- Incorrect **brand name** entered
- Incorrect **company code** or **company name**
- Incorrect **submission number** or **submission date** referenced
- Request submitted **after a Decisions has already been issued**
- **Unauthorized signing official** identified on the form



## Specific form issues:

- **Withdrawal Form:**
  - Incorrect selection of **withdrawal type**
    - Choosing the wrong option (processed vs. pre-processed) results in delays
- **NHPID Ingredient Request Form:**
  - The form does not support attachments
    - Supporting documents must currently be submitted by separate email after the form is submitted

## Changes being considered in wave 2\*

### Expanding the scope of Class II

- Example: include common spices, herbs, spices and tea ingredients, allow reliance on previous product licensing decisions during application review

### IRN and refusals

- Revisit IRNs in the context of refusals
- Introduce pause-the-clock mechanism and template for IRN response

### Statements to the effect of

- Allow for Class I applications

### Fundamental changes

- Apply flexibilities when proposed changes remain within the monograph's limits

### Classification of amendments

- Consider a risk-based approach to determining the class of an amendment application

### Notifications

- Separate from amendments through a dedicated form

### NHPID updates

- Timing relative to submission
- Inform users beyond the “What’s New” webpage

### Other system improvements

- Fix ePLA technical issues
- Consider alternatives to Connect (formally known as ePost Connect™) and current trading partner system

*\*List is not exhaustive as other changes have also been suggested. Presents key changes being considered.*