Regulatory Essentials – December 23, 2020

Cosmetics Alliance Update

Membership Renewal 2021

With 2021 fast approaching, we **need your involvement and commitment** with the renewal of your company's membership in order to help Cosmetics Alliance Canada advance the collective interests of the cosmetics and personal care products industry.

Steps to Renew

Pilot Certification Program with the Shark Water Foundation

Long time CA members Brian and Sandy Stewart of Tribute Entertainment continue the work of their late son, internationally acclaimed film-maker Rob Stewart of the Sharkwater Foundation who worked to raise awareness of the need to protect endangered shark species by ending the use of shark-derived squalene in cosmetics. CA will be working with the Sharkwater Foundation in the new year to scope a pilot certification program to ensure cosmetic manufacturers are sourcing plant-based squalene from suppliers. CA members interested in participating can contact mdavis@cosmeticsalliance.ca.

Health Update

Over-the-Counter and disinfectant product submissions over the holidays

This message applies to over-the-counter (OTC) and disinfectant companies with active drug submissions for which the review deadline falls between December 21, 2020 and January 10, 2021.

Health Canada has been expediting certain types of disinfectant drug submissions by at least 1-2 months, and some much faster than that, and processing non-COVID OTC and disinfectant applications without delay. They have consistently met their performance standard throughout 2020.

As the holidays are approaching, they are aware that many companies are temporarily closing their offices and will be unavailable to respond to Clarifax requests.

Typically, Health Canada would issue a negative decision if a Clarifax response is not received by the stated deadline, which does not include an allowance for holidays. Health Canada would like to avoid this outcome, while also avoiding missing performance standards. Similarly, for applications with a review deadline immediately after the holidays, Health Canada wants to ensure there is time allotted for them to issue, receive and review Clarifax responses.

Given this year's unique circumstances, for **all cost-recovered submissions** due between December 21 and January 10, Health Canada will be shifting the review deadline by 14 days. This 14-day deadline extension will also apply to submissions for which a Clarifax was issued prior to December 21, but remain unanswered by this date.

Throughout this period, Health Canada will continue to process submissions, including those with expedited review targets for qualifying disinfectant drugs. The decision to extend deadlines will support this work by allowing staff to focus on submission reviews, rather than managing submisison deadlines individually given we know a large number of companies will not be in a position to respond.

Sponsors are able to access information regarding their submissions via the Drug Submission Tracking System - Industry Access (DSTS-IA). To obtain a DSTS-IA account, or information about DSTS-IA, sponsors should contact OSIP at hc.client.information.sc@canada.ca.

If you have any concerns regarding a specific application, or do not wish to have review deadlines extended because you will be available to respond at this time, please contact NDED generic email at: hc.nded-demvso.sc@canada.ca.

Notification to Stakeholders: Web PLA version 4.1.0 deployment

Further to our notice on December 8, 2020 the 4.1.0 of the web-based Natural Health Product Licence Application (web PLA) form is now available. The new features in this version update enables validation of several more monographs including the Multi-vitamin and mineral supplements monograph.

Below is a summary of features and fixes new to version 4.1.0:

- New kit fields for kit applications
- Revised extract solvent options and requirements
- Revised modify ingredient options for 'Original Material Used' information
- Improved validation error messaging
- Fixed bugs with Homeopathic applications
- New feature that allows applicants to switch from Class I to Class II/III without losing progress
- Improved dose and dosage calculation logic
- Verification of synthetic versus non-synthetic medicinal ingredients in Class I monograph validation

The following 23 monographs have also been enabled with version 4.1.0:

- Aloe vera leaf gel - oral
- Amylase, alpha-
- Betaine / betaine hydrochloride
- Black walnut - juglans nigra
- Calendula - buccal
- Cranberry juice, dried
- Dandelion (Taraxacum Officinale) juice
- Fennel, bitter
- Flaxseed
- Flaxseed oil
- Joint health products, multiple ingredient
- Kelp products
- Multi-vitamin/mineral supplements
- Mushrooms
- Papain
- Plant sterol esters
- Primary sunscreen monograph
- Red clover isoflavone extract
- Secondary sunscreen monograph
- St. John's wort - oral
- Throat lozenges
- Willow bark
- Witch hazel - oral

NHP Licence Application Form User Guide has been updated to reflect the changes.

The list of validation-supported monographs can be found on the web PLA landing page. Applicants may begin using the web PLA form version 4.1.0 exclusively for all new product licence applications when attesting to any of the validation-supported monographs listed above in addition to those already on the list of validation-supported monographs.

DEL Bulletin LEPP No. 102 Consultation on the recommendations for interoperability of track and trace systems for medicines

The International Coalition of Regulatory Authorities (ICMRA) is seeking industry experts to comment on the recommendations put forward on interoperability of Track and Trace (T&T) systems for medicines. Health Canada, as a member of ICMRA, participated in the development of the recommendations.

ICMRA had established a working group to facilitate implementation of the recommendations document posted on the ICMRA website. This working group consisted of experts from both regulators and industry, who developed the draft recommendations in consultation with the Word Health Organization (WHO). ICMRA is now seeking stakeholder comments on the recommendations; this is an opportunity to contribute to the advancement of a public policy initiative and inform future directions on the alignment of the different T&T systems.

The draft recommendations are available for public consumption until **Feb 28, 2021**:

http://www.icmra.info/drupal/en/strategicinitatives/supplychainintegrity

Nitrosamine update to market authorisation holders of human pharmaceutical, biological, and radiopharmaceutical products

Please find attached an updated Q&A document to assist affected market authorization holders in responding to Health Canada's October 2, 2019 letter regarding nitrosamine impurities. This document also provides guidance to market authorization holders of biological and radiopharmaceutical products in their response to the attached December 15, 2020 letter on nitrosamine impurities.

HIGHLIGHTS:

- **Expansion** of product scope to Schedule D drugs (Biologics) and Schedule C drugs (Radiopharmaceutical). Timelines as follows:
    - Step 1 - Completion of risk assessments by November 30, 2021;
    - Step 2 - Confirmatory testing by November 30, 2023;
    - Step 3 - Changes to the market authorization by November 30, 2023.
- **Reminder**, for all other DINs (as communicated on August 10th, 2020):
    - Step 1 - Completion of risk assessments by March 31, 2021;
    - Step 2 - Confirmatory testing by October 1, 2022;
    - Step 3 - Changes to the market authorization by October 1, 2022.
- **What you can do if you can not meet the Step 1 deadline** (Question 7).
- The MAH letter dated December 15, 2020 highlights a number of **potential sources** of nitrosamine impurities which have been identified via root causes analyses and provides further guidance when conducting risk assessments
- The Q&A Document has been updated to include:
    - **New information**:
        - How changes to the market authorization should be submitted (Q12)
        - What the limits of quantitation that should be validated for analytical procedures for nitrosamine detection (Q28)
        - When routine testing for nitrosamines should be included in API and/or drug product specifications (Q29)
        - What potential control options there are for nitrosamine impurities in the API (Q. 30)
        - Details on the number of batches which should be tested as part of confirmatory testing (Q. 32)
        - What to do if multiple nitrosamines are detected (Q. 23)
        - Updates to acceptable intakes for nitrosamine impurities (Q. 21)

- **Updated information** has been added to the following questions: 1, 4, 7, 11, 14, 15, 17-20, 22, 24 and 26

HC Q&A Document on Nitrosamines EN/FR

MAH Letter English EN/FR

December 9, 2020- Performance standards for NHP applications

On December 9, 2020, the Natural and Non-prescription Health Products Directorate (NNHPD) of Health Canada held a meeting on *Performance standards for NHP applications* with NHP industry associations. Please find below the summary from that meeting as an update on the *Performance standards for NHP applications*.

NHP Performance Standard – EN/FR

Environmental Update

Various Publications Under the Chemicals Management Plan

Na3NTA

The draft screening assessment for glycine, N,N-bis(carboxymethyl)-, trisodium salt, also referred to as Na_3NTA, has been published. It is proposed to conclude that the substance does not meet any of the criteria set out in section 64 of CEPA.

While exposure of the general population to Na_3NTA is not of concern at current levels, the substance is associated with effects of concern. Therefore, there may be concern if exposure were to increase. Follow-up activities to track changes in exposure or commercial use patterns are under consideration.

- Draft Screening Assessment
- *Canada Gazette* Notice

Phosphoric Acid Derivatives Group

The final screening assessment for the Phosphoric Acid Derivatives Group has been published. It is concluded that these substances do not meet any of the criteria set out in section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA).

There is concern that significant new activities that have not been identified or assessed could lead to the substance trixylyl phosphate (Chemical Abstracts Registry Number 25155-23-1) meeting the criteria set out in section 64 of CEPA. The Government of Canada is proposing to amend the *Domestic Substances List* (DSL) to indicate that the Significant New Activity (SNAc) provisions under subsection 81(3) of CEPA apply to this substance.

- Final Screening Assessment
- *Canada Gazette* Notice for Final Screening Assessment
- *Canada Gazette* Notice of Intent to apply SNAc provisions