Regulatory Essentials – July 31, 2019

Health Update

CA Letter to Health Canada Deputy Minister – Self-Care & Request for Further Interim Relief

President and CEO of Cosmetics Alliance, Darren Praznik, wrote a letter to Deputy Minister Simmon Kennedy requesting for interim relief during extended finalization and implementation of the Self-Care Framework for the Sunscreen Pilot and ensuring companies do not have to re-label products twice under PLL and SCF. Specifically, CA has requested to expand Health Canada's Sunscreen Pilot to toothpastes, mouthwashes, anti-dandruff shampoos and other similar DIN products as identified in CUSMA and in the SCF and requesting that companies do not have to re-label products twice (under PLL and the SCF) incurring unnecessary costs before SCF implementation. Please take the time to review the letter below. Please let your CA Regulatory Team know if you have any questions.

Cosmetics Alliance Letter to DM Kennedy

Current Performance in Reviewing Site license Applications

The Natural and Non-prescription Health Products Directorate would like to update you on its current performance in reviewing site license applications. In addition, NNHPD would like to highlight measures that they encourage you to follow to help ensure the efficient processing of site licence applications.

Performance Against Service Standards

In March and April 2019, NNHPD did not meet the service standard for stream II applications (i.e. 58% and 45% of decisions were issued within the service standard, respectively). Although May's performance has not yet been tallied, it is expected to be similar to March and April. As such, NNHPD is currently in a backlog state and is, on average, picking up stream II applications for review on day 60. NNHPD is on track and meeting its service standards for both stream I and stream III applications.

For ease of reference, the service standards for site licence applications are as follows:

- Stream I: 35 business days;
- Stream II: 65 business days; and
- Stream III: 95 business days

For further information on the process, please refer to the Site Licensing Guidance Document.

NNHPD is putting measures into place, which include additional staffing and identifying process efficiencies, to improve its stream II performance. These actions, coupled with the recommendations below for applicants, should bring our stream II performance back in line with the service standard by the end of summer. That said, due to the volume of the backlog and to be fair to all applicants, NNHPD will not be in a position to entertain requests to prioritize an application.

Status Update Requests

In order to allow for the maximum number of resources to be dedicated to the review of site licence applications, we ask that you refrain from seeking an update on the status of your application, as these requests take significant time away from the actual review function and will cause further delays. This communique is intended to provide a general update to all applicants at this time on our performance.

Should a status update request be received by NNHPD, NNHPD will not respond if the application of interest is still within the performance standard. Please note, NNHPD will continue to check the status of all inquiries but will only respond to those that are over the service standard or have issues (e.g., not received).

Common Deficiencies

In 2018, Information Request Notices (IRN) were required to be sent for the majority of stream II and III applications (i.e., 82% and 98% of applications, respectively). Even stream I applications required an IRN 46% of the time. Site licence applicants can contribute to a more efficient application process by ensuring that their application does not contain deficiencies.

The most common deficiencies noted in IRNs are as follows:

1. **Missing summary of new changes (SNC) form.** For all renewals or new applications for companies that did not renew on time but have been in operation, an SNC form should be submitted, rather than a quality assurance report (QAR).
2. **Specifications** (Section 44 of the *Natural Health Products Regulations (*NHPR)) e.g., No finished product specifications, testing not aligned with specifications; specifications are incomplete and not in keeping with the Compendium and/or Quality of Natural Health Products Guide, as relevant.
3. **Stability** (Section 52 of the NHPR) e.g., No data provided to demonstrate the shelf life of the NHP.
4. **Quality Assurance** (Section 51 of the NHPR) e.g., Product released for sale in Canada without ensuring that it meets specifications; investigation not carried out into results that are out of specification.

Filing Applications Electronically

NNHPD is in the process of phasing out paper-based product licence applications. As of June 1, 2019, NNHPD only accepts product licence applications submitted electronically.

Electronic applications greatly increase NNHPD's efficiency, and this also holds true for site licence applications. As such, NNHPD strongly recommends that applicants submit site licence applications electronically, preferably through epost Connect™.

In order to send an application through epost Connect™, an applicant needs to be enrolled as a Trading Partner with NNHPD. Signing up takes less than five minutes and there are no costs associated with the use of this system. Further information about becoming a trading partner can be found here: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/natural-health-products/guidance-document-interact-natural-health-products-directorate-electronically-0-health-canada-2013.html.

Further guidance for submitting electronically to NNHPD is outlined in the Guidance document on how to interact with the Natural and Non-Prescription Health Products Directorate electronically.

Checking messages in epost

As part of the application process, NNHPD issues correspondence (e.g., acknowledgement letters, Information Request Notices, notices of licence issuance and refusal) through the epost™ messaging system. This system, which is a digital delivery platform with bank-grade encryption, facilitates the sending and receiving of confidential messages and documents with one or more recipient.

Applicants should regularly check their inbox and junk mail for emails from "epost™" or "Canada Post" once they have filed an application with NNHPD, to ensure that messages are seen and responded to within the requested timeframe.

Renewing a Site Licence

As per Section 36(1)(a) of the *NHPR*, an application to renew a site licence must be received **no later than 30 days before the day on which the licence expires**. Site licence renewal applications received less than 30 days prior to the site licence expiry date will be refused and the site licence will not be renewed.

That said, in keeping with the service standards established for site licence applications, and in light of the current backlog situation, NNHPD strongly encourages applicants to submit their renewal in accordance with the relevant service standard (i.e., 65 days for stream II applications).

For questions related to the submission process or site licensing requirements, we invite you to email them to hc.nnhpd-dpsnso.sc@canada.ca. Any concerns or questions about this communique can be submitted to Stephanie Reid, director of the Bureau of Licensing Services and Systems at stephanie.reid@canada.ca.

Publication of the Revised Monographs to Address Statements to the Effect Of

the Natural and Non-prescription Health Products Directorate (NNHPD) updated the following monographs to reflect the changes to the "Statements to the Effect of":

1. Gentian
2. Juniper
3. Lecithin
4. Thyme-Buccal
5. Thyme-Topical
6. White Birch

Please visit What's New Page to find a listing of modifications to the Natural Health Products Ingredients Database (NHPID) since the last update.

Revisions to the Administrative Processing of Submission and Applications Involving Human or Disinfectant Drugs

Health Canada revised the Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs. This document provides information for industry on how submissions and applications involving human or disinfectants drugs may be submitted for administrative processing.

The guidance is being updated at this time to clarify submission requirements for submissions processed administratively. Minor updates were made throughout to clarify requirements and update outdated information (e.g., contact information and web links). In addition, the following additions were made to clarify:

That for all drug submissions and applications for cross-licensed products, an Administrative Certification Form and a Letter of Authorization must be filed when applicable;

Requirements around when a Drug Notification form is required and when it will be issued/reissued; and

Labelling requirements including that for cross licensed products where an administrative submission is filed for labelling updates to match the licensor, mock ups do not need to be filed if certain parameters are met (refer to section 2.6).

This guidance document comes into effect immediately. Questions or concerns related to this guidance document should be directed to:

Bureau of Gastroenterology, Infection and Viral Diseases

Health Products and Food Branch

Therapeutic Products Directorate

Address Locator: 0201A1

101 Tunney's Pasture Driveway

Ottawa Ontario

K1A 0K9
Email: hc.bgivd.enquiries.sc@canada.ca

NNHPD Client Services Teleconference Call

Following up from the last teleconference call that took place on July 3, 2019, the Natural and Non-prescription Health Products Directorate would like to invite you to a 30-minute teleconference on either September 24, 2019 (1:00-1:30 pm) or September 25, 2019 (1:00-1:30 pm) to provide you with an update after the summer months.

If you would like to participate, please reply hc.nnhpd.consultation-dpsnso.sc@canada.ca indicating your availability for the above noted dates (September 24, September 25 or both days) by the end of day July 30, 2019. Please note that there will be only one teleconference call scheduled on the date where the majority of you are available.

The date of the call will be confirmed by July 31, 2019.

Agile Regulations for Advanced Therapeutic Products and Clinical Trials

The goal of this consultation is to seek feedback on what Health Canada should consider in developing new clinical trials regulations as well as implementing the pathway for Advanced Therapeutic Products. The department aims to continue the conversation with stakeholders and gather other ideas to help ensure our approach supports innovation while protecting the health and safety of Canadians.

How to participate

Send an email to hc.hpfb.engagement-mobilisation.dgpsa.sc@canada.ca to request the consultation information document and questions by email.

Who is the focus of this consultation

Health Canada wants to hear from:

- Academia
- Consumers/Patients
- Governments
- Industry
- NGOs
- Practitioners
- SMEs
- Other interested parties

Key questions for discussion

Please send an email to hc.hpfb.engagement-mobilisation.dgpsa.sc@canada.ca to request the consultation information document and questions by email.

Consultation Document

Environmental Update

Third Phase of the Chemicals Management Plan – Year 3 Work Planning Update

This letter is to inform you of the publication of year three updates to activities under the third phase of the Chemicals Management Plan (CMP). The third phase of the CMP is a five-year plan that began in April 2016. As outlined in the *Announcement of planned actions to assess and manage, where warranted, the risks posed by certain substances to the health of Canadians and the environment* published in the *Canada Gazette*, Part I, on June 18, 2016, Health Canada and Environment and Climate Change Canada are addressing certain substances to reduce related human health and environmental risks.

The updates cover the following activities, and are located on the Third phase of the Chemicals Management Plan webpage:

- Two-Year Rolling Risk Assessment Publication Plan (2019-2021);
- Two-Year Rolling Risk Assessment Publication Plan for the remaining existing living organisms to be assessed under CEPA (2019–2021); and

Two-Year Rolling Risk Management Activities and Consultations Schedule (2019-2021).

Please note that no updates have been made to the Two-Year Rolling Information Gathering Plan.

Various Publications Under the Chemicals Management Plan

Draft Screening Assessment and Risk Management Scope for Chlorocresol

The draft screening assessment of Chlorocrescol was released on July 26, 2019. The DSAR proposed to find Chlorocresol CEPA Toxic on the basis of human health concerns. The critical health effect for chlorocresol was identified as decreased adrenal organ weights in a chronic exposure study. A comparison of estimated exposure to chlorocresol from its use in cosmetics, such as body lotions, to the critical health effect level resulted in margins of exposure (MOEs) which were considered potentially inadequate to address uncertainties in the health effects and exposure databases.

With respect to dermal exposure to chlorocresol from the use of topical licensed natural health products or pharmaceuticals, a comparison of the estimated exposure to the critical effect level resulted in MOEs that are considered adequate to address uncertainties in the health effects and exposure databases. On the basis of this information, it is proposed to that Chlorocresol meets the criteria of CEPA as it is entering the environment in a quantity or concentration that constitutes a danger to human life or health.

Please let us know if you use Chlorocresol in your personal care formulations as it is critical to know the number of members affected by this DSAR. We will be reviewing the documents and will be preparing comments based on membership interest and feedback.

Requirements under the Significant New Activity Provisions

A notice of intent to amend the Domestic Substances List to vary or rescind the requirements under the Significant New Activity (SNAc) provisions for 110 substances was published for a 60-day public comment period ending on September 25, 2019.

Draft Screening Assessment for Dimethoxymethane

The *Draft Screening Assessment for Dimethoxymethane* was published for a 60-day public comment period ending on September 18, 2019.
On the basis of the information presented in the draft screening assessment, the risk to human health from dimethoxymethane is low.

Based upon the outcome of the Ecological Risk Classification of Organic Substances Approach, dimethoxymethane is considered unlikely to cause ecological harm.

The Government of Canada published the Draft Screening Assessment for Dimethoxymethane on July 20, 2019. The public are invited to comment on the assessment during the 60-day public comment period ending on September 18, 2019.

Dimethoxymethane is not considered to have hazardous properties for human health.

According to information considered under the Ecological Risk Classification of Organic Substances Approach, dimethoxymethane was identified as having a low ecological hazard potential.

Draft Screening Assessment for Acetic Acid

The *Draft Screening Assessment for Acetic Acid* was published for a 60-day public comment period ending on September 18, 2019. The Final Screening Assessment is anticipated to be released in July 2020. On the basis of the information presented in the draft screening assessment, the risk to human health from acetic acid is low. Based upon the outcome of the Ecological Risk Classification of Organic Substances Approach, acetic acid is considered unlikely to cause ecological harm.

As a result of the draft screening assessment, the Government is proposing that acetic acid is not harmful to human health at current levels of exposure, and that it is not entering the environment at levels that are harmful to the environment.

Update to the Two-Year Working Plan for the Third Phase of Chemicals Management Plan

Various documents for the two-year working plan for the Third Phase of Chemicals Management Plan. Specifically, the following documents have been updated:

- Chemicals Plan Implementation Timetable at a Glance – 2016-2021
- Two-year Rolling Information Gathering Plan (2018-2020)
- Two-year Rolling Risk Assessment Publication Plan (2019-2021)
- Two-Year Rolling Risk Assessment Publication Plan for the ramining existing organisms to be assessed under CEPA
- Two-year Rolling Risk Management Activities and Consultation Schedule

Please take the time to review these updates and let your CA Regulatory Team know if you have any questions.

Small and Medium-sized Business – Apply for Funding for Energy Saving Projects

The Minister of Environment and Climate Change, Catherine McKenna, announced that small- and medium-sized businesses in the four provinces where the federal government carbon-pollution pricing currently applies can now apply to the SME Project stream of the Climate Action Incentive Fund. Small and medium-sized businesses in these provinces will be eligible to receive funding of up to 25 percent of the cost of projects that will make their businesses more productive and competitive as they reduce energy use, save money, and cut greenhouse gas pollution.

A wide range of projects are eligible, including building retrofits, improved industrial processes, fuel switching, and the production of renewable energy for the use of applicants.

Over the next five years, small and medium-sized businesses in these provinces will have access to $1.45 billion to support actions such as increasing the energy efficiency of their operations.

This funding comes from a portion of the fuel-charge revenue from the four provinces where the federal price on carbon pollution is in effect.

The Government will soon launch a new call for proposals for smaller projects from small businesses across the country, under the Low Carbon Economy Fund Partnerships stream. Approximately $10 million will be available to help those businesses make investments to improve energy efficiency, reduce pollution, and save money.

Additional Clarity on the Survey of the Environmental Risk Assessment

The Health Products and Food Branch received an enquiry from a stakeholder regarding the proposed exclusion of disinfectants from the scope of the proposal. This email is intended to provide additional clarity with respect to this exclusion to all stakeholders, in order to ensure clarity in relation to the cost-benefit analysis (CBA) survey.

The Department regulates hard surface disinfectants and antiseptics for human and veterinary use under the Food and Drug Regulations. While filling out the CBA survey, please note that antiseptics for human or veterinary use that are required to submit applications under Division 8 are captured by this proposal, whereas hard surface disinfectants and Division 1 submissions are not. Health Canada is committed to collecting high quality cost-benefit analysis data prior to the pre-consultation period in Canada Gazette, Part I, and we appreciate your help in achieving that.

Post-Consumer Waste Update

Register Now for MHSW Wind Up Plan Consultation

Stewardship Ontario (S0) is holding two consultation webinars on **August 14 and August 20, 2019** after receiving further direction from the Ministry of the Environment, Conservation and Parks on the wind up of the MHSW Program. SO will be consulting on MHSW Wind Up Plan proposals consistent with the latest direction from the Minister, including new timelines for the program's termination, the implementation of a fee elimination for some MHSW categories and proposed options for the return of surplus funds to Ontario consumers of MHSM. Stakeholders may register using the following links below. Note that the same content will be presented at both webinars.

Wednesday, August 14, 2019

10:00 - 11:30 a.m.

Register here

Tuesday, August 20, 2019

1:30 - 3:00 p.m.

Register here

The webinar recording will be emailed to stakeholders and posted on the MHSW Wind Up page: https://stewardshipontario.ca/mhsw-windup/. Feedback will be accepted until **Friday, August 30, 2019** in order for Stewardship Ontario to finalize its MHSW Wind Up Plan and submit to the Resource Productivity and Recovery Authority (RPRA) by the Minister's September 30, 2019 deadline. If you have any questions, please contact SO at mhswwindup@stewardshipontario.ca.