Regulatory Essentials – November 25, 2020

Cosmetics Alliance Update

Last Session in this 3 Part NHP Series - Natural Health Product Good Manufacturing Practices

Date: Wednesday, November 25, 2020

Time: 2:00 pm - 3:30 pm EST

Cost: Member: $250 Non-Member: $395

Learn and Understand:

- What the elements of GMPs are
- What is required for GMPs?
- Product quality specifications and testing requirements

Each session will include exercises, a quiz, and a Q&A session.

Training Certificates are issued for your records to each individual successfully completing the quiz.

Individual logins are required for each participant to obtain a training certificate.

Register

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

Health Update

Temporary authorization for the use of technical-grade ethanol in hand sanitizer

In early April 2020, a scientific task force of government experts determined that the risk related to the use of technical-grade ethanol (TGE) for the production of hand sanitizers would be tolerable as a short-term solution to limit the spread of COVID-19. The authorization to supply technical-grade ethanol for use in hand sanitizer was originally set to expire on June 30, 2020.

In June 2020, Health Canada extended TGE authorizations, supported by a supply and demand analysis by Deloitte and an updated risk assessment by the task force to consider acetaldehyde levels of 11-400 ppm in authorized technical-grade products (originally 800 to 1000 ppm). Authorizations were extended until October 31, 2020 for suppliers of technical-grade ethanol, and until December 31, 2020, for hand sanitizer manufacturers using technical-grade ethanol.

With authorizations set to expire, NNHPD re-engaged the scientific task force and reviewed the evolving supply and demand context. The task force assessed the possibility to extend authorizations based on the risk of supply chain disruptions to USP and food-grade ethanol, and to consider if there was a tolerable level of acetaldehyde below which sanitizers made with technical grade ethanol could be used by children and women who are pregnant or breastfeeding. A summary of the updated risk assessment can be found here.

Health Canada is implementing the task force recommendations as follows:

- An extension from October 31, 2020, to March 31, 2021, will be given to authorized suppliers of technical-grade ethanol.
- An extension from December 31, 2020, to June 30, 2021, will be given to authorized hand sanitizer manufacturers to continue to use authorized technical-grade ethanol.
- Hand sanitizers using **authorized** technical-grade ethanol meeting specified levels of impurities, including no more than 75 ppm of acetaldehyde, no longer require additional label warnings
- The following TGE-specific warnings will remain in effect for hand sanitizers with more than 75 ppm acetaldehyde:
    - Adults only
    - Do not inhale
    - Do not use on broken or damaged skin
    - Not recommended for use by women who are pregnant or breastfeeding

For additional information on the authorizations to produce and distribute hand sanitizers, please refer to the notice to industry.

All suppliers, distributors and manufacturers supplying, distributing or using TGE for the production of hand sanitizers or hard surface disinfectants must continue to register regardless of the levels of acetaldehyde (above or below 75ppm) included in the ethanol

Before manufacturers can change their labelling for product made with technical-grade ethanol (TGE) containing below or equal to 75ppm of acetaldehyde, they must submit a new TGE Notification Form along with a Certificate of Analysis that demonstrates the TGE meets the policy requirements and the manufacturer must wait until issuance of the new No Objection Letter to start manufacturing.

The following extensions listed below apply to both supplier and manufacturer using TGE with levels of acetaldehydes above and below 75ppm.

- Extension from October 31, 2020, to March 31, 2021 inclusively, or until a notice is issued by Health Canada to licence holders (whichever is earliest), will be given to authorized suppliers of technical-grade ethanol.
- Extension from December 31, 2020, to June 30, 2021 inclusively, or until a notice is issued by Health Canada to licence holders (whichever is earliest), will be given to authorized hand sanitizer manufacturers to continue to use technical-grade ethanol from authorized sources. Manufacturers are expected to return to using USP or food grade ethanol (or ethanol of equivalent approved grades) for manufacturing hand sanitizer once the interim measure is lifted.

Please do not hesitate to contact the NNHPD Risk Management Division at hc.rmd.coordination-dgr.sc@canada.ca should you have any questions.

Web-Based Site Licence Application Form is Live

A new web-based site licence application was released on November 12th, 2020 to increase operational efficiencies.

- A new web-based site licence application form was released on November 12th, therefore if you are working on your site licence package and can wait to submit your application until after the new form is released, migrate to the new form, as long as you can still meet the 30 day deadline for a renewal.
- Do not submit paper-based applications, they will not be accepted after November 26th.
- Avoid submitting deficient applications. Applications will be refused if:
  - There is not site licence application form included.
  - If there is no GMP evidence included for any site which requires GMP evidence
  - If any portion of the application is in neither French nor English
  - You are unable to respond to an information request notice (IRN)
- Only include sites which are active sites.
- Withdraw inactive sites if an application has already been submitted
- Separate amendments and notifications from site licence renewal packages

For more information please click here.

Validation Rules for Transactions Containing the Regulatory Enrollment Process Company XML File

Health Canada has developed a set of validation rules for the submission of the Regulatory Enrollment Process (REP) Company (CO) XML file. These rules are built in accordance with the company enrolment information provided in the Guidance Document: The Regulatory Enrolment Process (REP).

The purpose of this document is to inform sponsors of the validation rules Health Canada will be using in order to assist sponsors in providing a valid electronic transaction to Health Canada via the CESG. Awareness and use of the validation rules to correctly submit a REP transaction will reduce errors and additional follow-up with sponsors. Sponsors are

encouraged to use a commercially available tool to validate the REP transaction containing the draft CO XML file prior to sending it to Health Canada.

Health Canada validates each regulatory transaction as it is received. If the validation fails due to errors detected, a Validation Report describing the errors will be sent to the sponsor in a.zip format.

Important Note: These rules are only for the transaction containing the draft CO XML file and must not to be used for regulatory transactions containing other REP files or regulatory documents submitted for review.

Beginning October 1, 2020, Health Canada will be using the Company XML validation rules version 1.0.

Should you have any questions regarding this document, please contact hc.ereview.sc@canada.ca.

DEL Bulletin LEPP No. 99: New COVID Hold for certain DEL Applications

Health Canada (HC) recognizes that the COVID-19 pandemic continues to have a significant impact on business operations. In particular, for certain DEL applicants, the pandemic has impacted their ability to host a drug Good Manufacturing Practices (GMP) inspection, which can affect timelines as set under the 2019 fee regime.

With the implementation of revised fees for drugs and medical devices on April 1, 2020, HC has been monitoring the 250-day service standard "clock" for the issuance of DELs. In circumstances where a GMP inspection is required as part of a DEL application and it cannot take place as planned, there are limited options under the regime to accommodate delays. To account for the unforeseen delays brought on by the pandemic, HC is implementing an interim "COVID hold" to introduce relief and flexibility that will offer the following benefits:

- Provide establishments impacted by the pandemic the opportunity to **have their DEL application put on hold, securing their place in the HC application queue** until such time that a GMP inspection can be conducted;
- **Avoid the need for affected DEL applicants to withdraw their DEL applications** while resolving issues caused by the pandemic (i.e. no need for affected applicants to start over and re-apply for a DEL);
- Continue to **protect the health and safety of both establishment personnel and HC inspectors** by respecting public health guidelines and restrictions in place to limit the spread of COVID-19.

This "COVID hold" feature would be applied when GMP inspections cannot be conducted due to either of the following reasons:

- Impacts on a drug **establishment's readiness for a GMP inspection** amid the pandemic (e.g. reduced staff, establishment shut down, inability to receive or set up necessary equipment, etc.), or

- Inability for HC inspectors to conduct a GMP inspection while respecting **public health guidelines and restrictions in place** due to the fluctuating COVID-19 situation within each Canadian province.

Does the "COVID hold" apply to foreign sites?

Given the current public health guidelines and travel restrictions, HC has postponed foreign on-site GMP inspections until further notice, therefore this interim "COVID hold" feature will not apply for foreign sites. However, DEL Bulletins 75 & 84 outlined flexibilities that HC is offering to DEL holders/applicants with respect to foreign site evidence. Namely, HC has introduced flexibilities to the requirements of GMP evidence for foreign buildings including but not limited to extending the New Evidence Required BY (NERBY) dates for foreign building evidence, extending the "age" of inspection reports to demonstrate GMP compliance of foreign buildings (from 3 years to 5 years) and considering corporate/consultant audits. Additional details can be found in DEL Bulletins 75 and 84.

Is there a time limit for this "COVID hold" feature and where do I send feedback during its implementation?

This interim "COVID hold" feature will apply to new DEL applications and amendments to existing DELs for the duration of the pandemic, as required. HC will notify applicants whose applications have been put on "COVID hold".

To offer ongoing flexibility to DEL applicants during these challenging times, HC will not be imposing any defined time limit for "COVID holds" applied on a DEL application for the duration of the pandemic.

Environmental Update

Various Publications under the Chemicals Management Plan

The Final Screening Assessment for in Inorganic Substances of Low Concern and the Draft Screening Assessment for Sucrose Acetate Isobutyrate was published on November 16, 2020.

FSAR of Inorganic Substances of Low Concern:

Of relevance to the personal care products industry of the Inorganic substances in the FSAR are Potassium iodide, Hydrogen peroxide and Barium Sulfate. It is concluded that all of the 21 substances tested has a low likely hood of causing harm to human health and environment and does not meet any of the criteria under Section 64 of CEPA.

DSAR of Sucrose Acetate Isobutyrate:

The screening assessment summarized here focuses on the substance α-D-Glucopyranoside, 6-O-acetyl-1,3,4-tris-O-(2-methyl-1-oxopropyl)-β-D-fructofuranosyl, 6-acetate 2,3,4-tris(2-methylpropanoate), also referred to as sucrose acetate isobutyrate (SAIB), and corresponding to CAS RN 126-13-6. SAIB is used as an adhesive and film forming agent in cosmetics and is a permitted food additive. It is also listed as an ingredient permitted in natural health products. It is proposed that SAIB has a low risk to humans and the environment.

Inorganic Substances of Low Concern
The Final Screening Assessment is now available on the Canada.ca (Chemical Substances) Website.

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/inorganic-substances-low-concern.html

Sucrose Acetate Isobutyrate
The Draft Screening Assessment is now available on the Canada.ca (Chemical Substances) Website.

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/sucrose-acetate-isobutyrate.html

Over 50 environmental groups receive support for freshwater protection initiatives through EcoAction

The Minister of Environment and Climate Change, the Honourable Jonathan Wilkinson, and the Member of Parliament for West Vancouver–Sunshine Coast–Sea to Sky Country, Patrick Weiler, announced approximately $4 million to support 53 new projects under the EcoAction Community Funding Program.

All 53 projects focus on protecting the health and quality of water. Some projects tackle chemicals in the water; others restore damaged wetlands; the remainder boost our ecosystems so that they have additional capacity to handle floods that are more frequently occurring due to the impacts of climate change. The funds will also support various communications and public-engagement initiatives aimed at ensuring that local communities have the tools they need to protect their water and related ecosystems.

These are the types of projects underway with the government as part of their key environmental action agenda. This initiative could be an important early warning indicator

on the focus of future funding initiatives and the direction for the future such as plastics and microplastics which is front and centre in this initiative.

However, missing is funding to help support programs to support communities and consumers for responsible management of waste (including plastic waste) and would have been great to have some initiative towards education/awareness programming.

Other Update

Influencer Marketing: Ad Standards & The Competition Bureau

Date: Tuesday, December 15, 2020

Time: 1:00 - 2:00 p.m. ET

Price:

Free for Ad Standards Members

$20+tax per person for Non-Members

Register

Learn more about the rules that apply to influencer marketing, and how to stay on the right side of applicable laws and industry self-regulation. Ad Standards is pleased to welcome **Josephine Palumbo, Deputy Commissioner of the Competition Bureau's Deceptive Marketing Practices Directorate**, to join us for this highly anticipated program. In this session, you'll hear more about:

- Recent updates to Ad Standards' Influencer Disclosure Guidelines, and how to apply them
- Outreach initiatives that the Competition Bureau has undertaken in this area
- What is required of influencers, and the advertisers who engage them, under law and self-regulatory standards
- Some of the most common pitfalls that arise around testimonials and reviews in advertising
- Practical tips to apply to future executions and best practices

This event will be presented in English.

Please note, the access info for this Zoom Webinar will be shared with registrants via an Eventbrite email on Monday, December 14