Regulatory Essentials – July 22, 2020

Cosmetics Alliance Updates

Cosmetics Alliance Interactive Training Series

How to Use the Web-Based Product Licence Amendment and Notification (PLAN) Form

Date: Wednesday, August 5, 2020

Time: 2:00 pm - 3:30 pm

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

Learn and Understand:

- What you need to do prior to submitting using the PLAN
- How to navigate and use the PLAN
- The resources available at Health Canada on using the PLAN
- How to submit the PLAN for gaining market access
- Where the PLAN is headed under the Self-Care Framework

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

Guidance for Re-opening Cosmetics Retail

As “in-person” cosmetics retail has begun to re-open, it is important that good practices are in place to help reduce the risk of spreading COVID-19!

Cosmetic Alliance has developed member Guidance for Re-Opening In-Person Cosmetics Retail which is now posted to our new Re-Opening Resource Centre on CA's members-only website.

The materials developed are intended to help industry understand and mitigate the risk of exposure to the coronavirus. Our objective is to assist in promoting the safety of beauty advisors and direct sellers (including other service providers and brand representatives), as well as their customers and clients.

With the help of subject experts, international partners, and other trade associations facing similar issues, as well as with member input, CA has prepared guidance materials that members can use to assist in their re-opening and training of staff. Information includes recommendations, check-lists, and detailed resource references related to cosmetics retail, the beauty advisor (at the beauty counter), the direct seller (in-home), and customer/client interactions (e.g. product demos, makeup tools).

Please click HERE to access the materials.

The CA Team hopes that members find these resources helpful! Should you have any questions or comments, please don't hesitate to contact your CA Team!

Health Updates

Information Session - Notice of Proposal to expand the lists of certain products for distribution as samples

As mentioned in CA's Update on the implementation of the Canada-United States-Mexico Agreement (CUSMA) sent to members on June 30th, Health Canada will be holding a bilingual information session to provide details on the imminent publication of a Notice of Proposal to expand lists of certain products for distribution as samples.

The bilingual information session will be held on July 23, 2020 from 1:30 pm to 3:00 pm EST.

To attend the information session, you must register in advance, as spaces are limited.

To register for the Information Session on July 23, please click Register.

Once your registration is confirmed, you will receive an email with instructions for joining the information session.

If you have any questions, please contact the Natural and Non-prescription Health Products Directorate at: hc.nnhpd.consultation-dpsnso.sc@canada.ca.

NNHPD Withdraws Interim Measures for Alcohol-based Hand Sanitizers

The Natural and Non-Prescription Health Products Directorate (NNHPD) of Health Canada issued a Notice informing stakeholders of the elimination of their interim measures related to expedited product and site licensing for alcohol-based hand sanitizers.

Recall that back in late March, NNHPD introduced interim measures to enable expedited product and site licensing for alcohol-based hand sanitizers to address the shortage of these products during the coronavirus pandemic. These measures provided companies that intended to manufacture, package, label and/or sell alcohol-based hand sanitizers with a simplified pathway to obtaining the required authorizations.

Health Canada has since completed a forecasting analysis of the supply and demand of alcohol-based hand sanitizers and has determined that there is currently sufficient domestic production capacity to meet the demand over the next 12 months. Additionally, NNHPD recently launch their new web form providing electronic validation of Class 1 NHP applications. As such, NNHPD has informed stakeholders that they will now resume regular service standards and requirements for new product and site licence applications for alcohol-based hand sanitizers.

What does this mean for current product licences and interim COVID-19 site licences?
– all existing licences remain valid; no action is required at this time from license holders
– NNHPD will process amendment requests for interim site licences with the normal service standard of 35 business days
– to continue to sell an authorized alcohol-based hand sanitizer beyond the end of the pandemic, a valid site licence will be required

Please refer to the Notice for additional information for future product and site licence applicants of alcohol-based hand sanitizers.

Notice to Stakeholders Regarding the AHA/PHA Entry on the Cosmetic Ingredient Hotlist

We were made aware by CHPSD that they would be issuing a Notice to Stakeholders (NtS) regarding clarifications to the NtS sent to stakeholders on January 13 with possible hotlist amendments that they were contemplating for 2020 (following up on information they tabled during our regulatory work shop and which we notified members of (December 12, 2019). Before CA could obtain additional context from CHPSD on this clarification Notice, we understand it has already been sent to all stakeholders – although we have not yet received a direct copy.

OUR CONCERN

We are very concerned with this revised NtS because CHPSD has stated that there is not enough science to support the differentiation of AHA/PHA and therefore are considered to have the same physical and chemical properties. Thus, PHA entry will be the same as the AHA entry. As you are aware, through the work we are doing with our AHA/PHA Science Task Force, we have been consolidating our technical submission looking to differentiate these ingredient classes and have been actively seeking a science meeting with Health Canada to discuss the science that they are claiming is not enough to support this differentiation. We are understandably very disappointed that Health Canada has elected to send out this clarification in advance of allowing this science input to come to the force.

The wording of the NtS is very worrying as it appears pre-emptive (i.e. it is there opinion already that there is no available science to differentiate between AHAs and PHAs). By presenting this clarification in this manner, officials are effectively signaling that they are proceeding with this interpretation, regardless of the fact that it exactly this premise that their original notice was intending to explore and look to differentiate – if their minds are already made up, what's the point of pre-notifying stakeholders of their thinking and to 'consult'?

Unfortunately, the net impression left with this clarification NtS is that the decision has been made and stakeholders should comply with NtS moving forward. CA will be reaching out urgently to CHPSD to seek clarification on the overall intent of this NtS and encourage them not to short-change the process and allow for the consultation to proceed.

POSSIBLE INTERIM COMPLIANCE PROMOTION ACTIVITIES

In the interim, we understand that Health Canada, as part of their Cyclical Enforcement Project maybe targeting AHAs. These compliance promotion activities should be based on the current state of affairs and should not extend or reflect and considerations for policy that is presently under development (i.e. consultation). On this basis, any Cyclic Enforcement project should only be focused on AHAs at this time.

RECOMMENDATION FOR MEMBERS IF AN INSPECTOR COMES CALLING REGARDING AHAs or PHAs IN YOUR PRODUCTS

If an inspector contacts you over this matter and requests to tests products containing AHAs or PHAs, remember we are within their rights to inquire and limit scope implicated by what is on the hotlist today… not what could be on the hotlist tomorrow. For officials to insist otherwise

would be inappropriate and we recommend that members reiterate such limitation in scope. It makes no sense to promote compliance on a matter which is still under consultation and being discussed for which only a notice of intent has been published. The whole point of the hotlist amendment process that we have been negotiating over the past few years is to enable meaningful, active and practical consultation before action is undertaken.

CA's Next Steps:

CA appreciated that members are likely to be concerned with the wording reflected in this clarification notice and we are following up accordingly to secure the following:

- CA will seek clarification from CHPSD on the intent of the NtS
- CA will ensure CHPSD allows for an appropriate and clear process for the PHA entry (pre-consultation, consultation, final amendment)

In the interim, please let us know if this activity hits your doorstep. Please review the clarification NtS when it arrives and do not hesitate to follow-up with your CA Regulatory Team if you have any questions or would like to discuss these developments further (regulatory@cosmeticsalliance.ca).

Good Manufacturing Practices for Drug Products (GUI-001) Updated

Health Canada has updated the Good Manufacturing Practices for Drug Products (GUI-0001) located at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001.html.

This update reflects the new Finished Product Testing Regulations (C.02.019) to reflect changes to the GMPs under the Canada-US-Mexico Agreement (CUSMA).

Rationales and Interpretations for these new regulations are expected in the coming weeks in a revision to Annex 1 to the Current Edition of the Good Manufacturing Practices Guidelines - Selected Category IV Monograph Drugs (GUI-0066).

DEL Bulletin No. 90 – GUI-0005 Explanatory Notes for Drug Establishment on the Preparation of a Site Master File

On July 17th, 2020 the Health Products Compliance Directorate posted the following guidance document to the Health Canada website:

- *Explanatory notes for drug establishments on the preparation of a site master file (GUI-0005).*

GUI-0005 is a revised version of the currently posted document replacing *PIC/S Annex 1: Explanatory Notes for Industry on the Preparation of a Site Master File document* (January 18, 2008). GUI-0005 will be implemented effective immediately as it will help you prepare a site master file.

This guide is based on the Pharmaceutical Inspection Cooperation Scheme (PIC/S) document *Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File (SMF) (PE 008-4*). This guide reflects changes necessary to adapt the text of the PIC/s document to meet Canadian requirements.

Drug and Medical Devices Mid Year Update

Learn about Health Canada's work to support Canada's response to COVID-19, the new drugs and medical devices that Health Canada approved for sale in Canada and clinical information published. Over the past 6 months, Health Canada's focus has been mainly on supporting the fight against COVID-19. This pandemic has created an unprecedented demand on Canada's health care system. Health Canada has played a key role in Canada's response to COVID-19 by working with partners and stakeholders to ensure essential health products and medical supplies are available for Canadians.

Early on, Health Canada implemented innovative and agile measures to help prioritize and expedite the regulatory review of COVID-19 health products. They did this without compromising Canada's high standards for safety, efficacy, and quality. They continue to work with domestic and international players to help accelerate the development and availability of drugs and vaccines that will prevent and treat COVID-19.

In addition to supporting Canada's response to COVID-19, they also continued to authorize many other drugs and medical devices. These health products are vital to the health and well-being of Canadians.

Lastly, Health Canada recently published their 5th annual Drug and Medical Devices Highlights Report. Please see Drug and Medical Device Highlights 2019: Helping you Maintain and Improve your Health to learn more about our accomplishments in 2019.

Environmental Updates

Draft Screening Assessment of Alkanolamines and Fatty Alkanolamides Group

The Draft Screening Assessment for the Alkanolamines and Fatty Alkanolamides Group was published for a 60-day public comment period ending on September 16, 2020. The Draft Screening Assessment concludes that Alkanolamines and Fatty Alkanolamides Group is not CEPA toxic.

Protection of Canadian Workers from Exposure to Chemicals

A summary of feedback from the consultation: An integrated strategy for the protection of Canadian workers from exposure to chemicals was published.

On July 11, 2019, Health Canada (HC) launched a 50-day online consultation, which invited interested stakeholders and the general public to provide comments on the Government of Canada's proposed actions and opportunities to expand, strengthen and integrate existing approaches, and on how to best protect Canadian workers from exposure to chemicals of concern.

Cosmetics Alliance will be reviewing the consultation and will be engaging on this topic at the ICG as CEPA Review continues. Cosmetics Alliance will continue to monitor any developments and will inform membership accordingly. We welcome any feedback you may have on the consultation published. Your input is critical since the feedback received will shape our follow-up with Health Canada and the ICG.

Please note Health Canada has not directly reached out with any specific requests for the additional monitoring that they are considering. However, we are aware that EAs are one of the analyte groups that is often included in the Canadian Health Measures Survey since they are targets of NGO organizations. Given the proposed conclusion this is a good indicator that Health Canada will continue to monitor as required to ensure volumes do not change.