Regulatory Essentials – May 27, 2020

Cosmetics Alliance Updates

Update from the Hand-Sanitizers Manufacturing Exchange

As indicated in our last update (#5, May 02,2020), given the increasing number of manufacturers listed with the exchange, we have now moved to a new format for providing manufacturers with supplier information. Please see below for important updates from the Cosmetics Alliance Exchange Program.

https://myemail.constantcontact.com/Update-from-the-Hand-Sanitizers-Manufacturing-Exchange.html?soid=1102801646439&aid=mNUvT12Z2RM

Free Member Webinar: Cosmetics Safe Re-Opening Initiative Developing Safety Guidance for Re-Opening Cosmetic Retail

Date: Thursday, May 28th for Interested Members

Cost: Free for Members

As governments and public health officials contemplate the safe re-opening of retail business, CA has taken the initiative to develop industry guidance and best-practices on how this can best be done to protect the safety of your staff and customers. The intent of this effort is to assist public health officials in understanding and addressing the unique aspects of cosmetic retailing to best ensure the safety of beauty advisors, direct sellers and our customers.

The **Cosmetics Safe Re-Opening Initiative** will be holding a Webinar open to all CA members on **Thursday, May 28** from **2:00 – 3:30 p.m.** The webinar will include a review of the proposed process for moving forward as well as a presentation on the draft materials currently being collected and prepared with the help of subject experts, international partners, and other trade associations facing similar issues. Participants will be asked to contribute to this effort by providing their feedback that can then be incorporated into the draft materials.

Some of the specific areas to be addressed include:

- Safety in the retail space
- Safety for service providers
- Safety for customers/clients
- Safety requirements for a controlled product demonstration or make-over
- Hygiene for products and tools
- Safety for direct sellers and their customers in a non-retail setting

The final guidance/best-practices coming out of this process can be used for providing appropriate staff training as required

Health Updates

Health Canada Updates Interim Measures for Hand Sanitizers - Including Unilingual Flexibilities and Expedited Licensing Performance Standards

On May 13, Health Canada made the following changes to their COVID-19 pandemic interim measures for hand sanitizers:

1. The allowance of unilingual labelling has been eliminated, and
2. Reference to a 24-48 hour turn-around time for product and site licence applications under their expedited licensing approach has been deleted.

Background:

Given the shortage of hand-sanitizers in the Canadian marketplace and industry's eagerness to help in the COVID-19 pandemic, Health Canada (HC) established an expedited licensing approach for alcohol-based hand sanitizers to assist the fight against the COVID-19 pandemic. Through this expedited process, HC has issued market authorizations for the manufacture and sale of over 1,900 hand sanitizer products! Another flexibility provided by HC allowed for domestic hand sanitizer manufacturers to use unilingual labelling.

In light of the short-term success in meeting an unprecedented demand and urgent need for disinfectants and hand sanitizers during the COVID-19 pandemic, the following interim measures are being changed.

BILINGUAL LABELLING

Please read carefully to determine which scenario applies to your business.

1. In order to benefit from the interim measures, importers of disinfectants and hand sanitizers will be required to post bilingual label text on their website and provide sellers with a means to inform consumers, at the time of sale, of the website where bilingual label text is posted. This could be made available through a sticker applied directly to the products, or posters or signage with take-away pamphlets at the point of sale. **Effective immediately**, all NEW importers of these products through the interim measure must meet this requirement. All importers PREVIOUSLY AUTHORIZED must meet this requirement no later than **June 8, 2020**.

2. Effective immediately, all NEW Canadian manufacturers of disinfectants and hand sanitizers must use bilingual labelling. Canadian manufacturers of hand sanitizers who are CURRENTLY LICENSED and are using unilingual labelling under the interim measure will be required to adopt bilingual labeling no later than **June 8, 2020**.

3. HC will take a risk-based approach to addressing any non-compliance identified.

This updated approach is posted on HC's website **HERE**.

NOTE: Products that are already in the distribution channel or at retail will be allowed to sell-through. The June 8, 2020 date is not a point-of-sale deadline. All product entering distribution channels after June 8, 2020 should feature bilingual labels.

CA continues to be engaged with Health Canada to keep these flexibilities for products imported or manufactured for internal use within domestic operations and "behind-the-counter" workplace settings (e.g. beauty counters).

UPDATED PROCESSES & GUIDANCE

The 24-48 hour turnaround time for product licence and site licence applicants has been removed. The expectation is now 5 – 7 days. We encourage you to follow-up with officials as we have previously directed in our communications if this timeline has been exceeded.

Links to HC's updated document are as follows:

Hard-surface disinfectants and hand sanitizers (COVID-19): Information for manufacturers

Guide on Health Canada's interim expedited licensing approach for the production and distribution of alcohol-based hand sanitizers

Interim guide on the production of ethanol for use in alcohol-based hand sanitizers

NEXT STEP – ADDRESSING NON-COVID APPLICATION BACKLOG

We will be working through our Product Compliance & Market Access (PCMA) committee for assistance on how to approach the mounting backlog of non-COVID submissions in a fair and transparent manner.

The NNHPD has acknowledged that nearly their entire focus over the past few weeks has been on CoVID-related activities such as reviews and approvals and they have openly confirmed (as many of you already realize) that there is now a significant backlog of outstanding reviewers related to non-CoVID related submissions

If you are a member of our PCMA committee, please stand by for an invite to this meeting. In advance of the meeting, please come prepared with ideas on:

– How HC can begin to address the backlog
– How best to prioritize the queue given different relative "urgencies"
– Any input/suggestions we may wish to present to the NNHPD for consideration

If you are not a member of our PCMA committee and wish to become a member, please reach out to us at regulatory@cosmeticsalliance.ca.

If you have any questions, please don't hesitate to contact your CA Regulatory Team.

DEL Bulletin LEPP No. 86 Guidance on Transportation and Storage Considerations and Additional Measures for Operational Relief amid COVID-19

Health Canada continues to work closely with the Public Health Agency of Canada, which is leading the COVID-19 public health response and pandemic planning as well as with provincial, territorial and international partners to monitor and respond to this evolving situation.

Health Canada realizes that it is critically important to take the additional steps at this time to ensure Canadians have continued access to the medication they rely upon. This DEL Bulletin has been issued as part of our ongoing monitoring of the current challenges industry is facing and will provide you guidance on the following three items:

- Transportation and Storage Considerations
- Deferral of Low Risk Investigations
- Document Approvals when Working Remotely

Transportation and Storage Considerations

Canadian importers, distributors, and wholesalers must ensure that shipping conditions will not impact the safety, efficacy, or quality of the drugs that Canadians rely upon.

Health Canada is aware of challenges encountered when shipping medications as shipping modes and routes have been affected by the COVID-19 pandemic. This may lead to Canadian suppliers having to use new shipping modes or routes. Please ensure such changes are evaluated in accordance with Quality Risk Management (QRM) principles and consider the following:

- ✓ Evaluate the new shipping route/mode to determine potential risks and potential extreme environmental conditions.
- ✓ Review known information about the product, such as all stability data and freeze/thaw and high temperature cycling studies, where available. *Note: If wholesalers do not have access to such information, they should seek guidance and recommendations from their suppliers.*
- ✓ Apply mitigation strategies for any identified risks. This should include a consideration to increase temperature monitoring points throughout the load to better assess transportation conditions.
- ✓ Review and update your risk evaluations periodically.

Health Canada is aware that, due to the pandemic, you may be experiencing additional challenges such as unavailability of temperature mapped vehicles and containers, a potential lack of warehouse space, and a lack of personnel to conduct required qualification and calibration activities. Please consider the following to mitigate these challenges:

- ✓ Conduct a QRM assessment to determine if distribution equipment and facilities can be used in an expedited manner with limited qualification and validation. In such cases, additional mitigation steps (e.g. increased temperature monitoring) may be required. Any remaining qualification and validation work should be completed as soon as possible.
- ✓ Defer periodic calibration requirements when there is a minimal risk of failure per a QRM assessment. You should continue to check devices periodically to ensure they are working within established temperature and humidity limits.

Additional Measures for Operational Relief

Deferral of Low Risk Investigations

Holding batches of products with shortage concerns to allow the completion of minor or low risk investigations may not be practical or appropriate during the COVID-19 pandemic. However, it is critical that you:

- ✓ Assess all incidents to determine any product quality impact. Any incident potentially impacting batch quality must be appropriately investigated.
- ✓ Track and trace all incidents. Although investigations of minor incidents may be deferred, you should investigate and action all negative trends in a timely manner.

Document Approvals when Working Remotely

During the pandemic, you may have a significant number of staff working from home and quality and service consultants not able to visit sites. Health Canada understands that this is creating difficulty as not all companies have the appropriate controls in place for electronic

signatures as per *Good manufacturing practices guide for drug products (GUI-0001).* In response to such challenges, Health Canada will not object to the implementation of electronic records and systems that do not fully meet *Good manufacturing practices guide for drug products (GUI-0001)* provided that steps are taken to ensure their authenticity. Examples of such steps include:

- ✓ Ensure all electronic signatures are controlled and fully attributable to the person signing the record.
- ✓ Ensure all personnel understand the meaning of electronic signatures.
- ✓ Ensure all electronic signatures are dated. Electronic signatures should also be time-stamped, where possible.

Important: It remains the responsibility of the Canadian Quality Control department to ensure all drug product complies with the *Food and Drugs Act*, the Food and Drug Regulations and applicable marketing authorizations.

For any questions on this approach or to raise any challenges experienced, please email hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca.

Guidelines for Temperature Control of Drug Products During Storage and Transportation (GUI-0069)

Cosmetics Alliance Updated Hand Sanitizer Interim Measures – Questions and Answers

Cosmetics Alliance recently updated its Hand Sanitizer Interim Measures – Questions and Answers document as reflected in Health Canada recent communication around Additional Clarification and Requirements to March 17 DEL Bulletin # 74. Please click below for the updated document.

https://www.cosmeticsalliance.ca/cosmetics-alliance-updated-hand-sanitizer-interim-measures-questions-answers/

Post-Consumer Waste Updates

Blue Box Program Transition Plan Consultation Webinars Rescheduled

As you know, the Minister of the Environment, Conservation and Parks directed Stewardship Ontario to wind up the Blue Box Program and develop a Transition Plan whereby stewards will be made fully responsible for both the funding and operation of residential recycling in the province under the *Resource Recovery and Circular Economy Act, 2016*.

As per the recent Minister's extension letter, the Transition Plan is to be submitted to the Resource Productivity and Recovery Authority (RPRA) by August 31, 2020. The Minister anticipates RPRA will approve the plan no later than December 31, 2020.

The April Blue Box Program Transition Plan consultation webinars that were postponed due to the evolving COVID-19 situation have been rescheduled to June 16 and 17, 2020.

They will be hosting three webinar consultations, focused primarily on matters affecting specific stakeholder groups during transition:

Tuesday, June 16, 2020

Steward community

10:00 - 11:30 a.m.

Register here

Municipalities, First Nation communities and the waste management industry

1:00 - 2:30 p.m.

Register here

Wednesday, June 17, 2020

Environment non-government organizations and other stakeholders

1:00 - 2:30 p.m.

Register here

The consultation webinars will be an opportunity to review and comment on how Stewardship Ontario intends to implement the Minister's direction outlined in his August 15, 2019 letter, including:

- Demonstrating transparency and meaningful consultation.
- Supporting competition and preventing conflict of interest.
- Demonstrating fairness to stewards and protecting consumers; and
- Maintaining program performance.

Other matters of interest to be presented include:

- The proposed process and timelines for transition and related costs.
- The proposed approach to ensure continuity of funding for municipalities.
- Anticipated changes to the method Stewardship Ontario are proposing to determine steward fees during transition; and
- How reserve funds will be applied to offset transition costs and steward fees.

Your involvement and feedback will be essential as they work towards finalizing the Blue Box Program Transition Plan.

Any questions please contact consultation@stewardshipontario.ca