Regulatory Essential - April 1, 2020

Cosmetics Alliance Updates

CA Launches Hand-Sanitizers Manufacturing Exchange Program

Cosmetics Alliance, along with the Canadian Consumer Specialty Products Association and the Canadian Distillers Association, are pleased to launch the *Hand-Sanitizer Manufacturing Exchange.*

At the urging of Health Canada and Canadian Manufacturing & Exporters, we have been encouraged to assist in matching manufacturers with suppliers of ingredients, components and supportive services to maximize the domestic production of all-important hand-sanitizers during the COVID-19 pandemic.

If your company has manufacturing capacity but requires ingredients, components or supportive services; or if you have ingredients, components or supportive services available this Manufacturing Exchange can help make the match to GET the JOB DONE!

NOTE: Given that time and effort are also in demand, if you belong to more than one participating trade association you need only access the *Exchange* through one website as "we are all in this together"!

Details can be found here

Health Updates

DEL Bulletin LEPP No. 75 Approach to Management of COVID-19

Health Canada has been working 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.

The Health Products Inspections & Licensing (HPIL) division will be focusing on critical services directed at facilitating responses to the COVID-19 pandemic to protect the safety of all Canadians. As such, some non-critical services such as DEL applications and GMP inspections will be temporarily deferred.

For the time being, Health Canada's HPIL operations will be focussed on requests related to medically necessary drugs as well as drugs that have been deemed important to mitigate the risks of COVID-19. These products may include antibiotics and antivirals, as well as critical treatments for various diseases.

To help us prioritize requests, please include "COVID-19" or "MEDICALLY NECESSARY" in the subject line of any email correspondence regarding critical products.

Drug Establishment Licence (DEL) applications
This temporary shift in focus to mitigate the impacts of COVID-19 is expected to affect the processing of regular DEL applications.

To ensure your package is processed as efficiently as possible, from today and until further notice, when submitting a DEL application, please clearly indicate the following in your cover letter to help us prioritize applications:

- The drug brand name
- The drug identification number (DIN)
- The drug active ingredients

In addition, Health Canada is informing you that the NERBY date of all foreign buildings with an expiry date between March 10, 2020 and June 1, 2020 is being extended to July 1, 2020 effective immediately. Health Canada will not issue updated DELs to reflect this extension, the extension being granted by way of this communication.

Similarly, the deadline for submitting an Annual Licence Review Application is being extended to July 1, 2020 by way of this communication.

Domestic & Foreign Inspections

Health Canada is postponing health product domestic GMP inspections previously scheduled for March 2020, and postponing foreign inspections previously scheduled through June 2020.

As the situation continues to evolve, Health Canada may consider conducting inspections on a case-by-case basis, as needed. Health Canada will continue to monitor the situation, remain flexible, and adapt the approach to continue to ensure the health and safety of Canadians.

In addition, please note that Health Canada will take into consideration the delay of planned inspections by qualified/regulatory authorities, as well as the inability to find a qualified auditor to conduct a corporate/consultant audit due to the COVID-19 pandemic, for any outdated GMP evidence listed on your Table A.

Impacts to your operations

Health Canada acknowledge that companies may experience challenges as a result of the COVID-19 pandemic. Responses to theses challenges should be based on an appropriately documented quality risk assessments and/or in accordance with your firm's quality system requirements.

Health Canada would also like to remind you of your ongoing responsibility to report any anticipated or actual drug shortages (see DEL Bulletin No. 71 sent February 19, 2020), in particular, shortages of products pertaining to the COVID-19 response.

<u>DEL Bulletin LEPP No. 76 Health Canada announces interim drug product testing measures for licensed importers</u>

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. As such, new interim approaches are being introduced to prevent delays in the release of product to the Canadian market after importation into Canada from non-MRA countries. The measures will also ensure that medications sold in Canada continue to have appropriate product quality oversight.

Effective immediately, and until further notice, all importers of drugs licensed under Division 1A of the *Food and Drug Regulations* may:

1. **Apply expanded use of unique identifiers to allow for confirmation of identity based on physical verification:**
    - When laboratory testing is required for identification purposes, but is not readily available, companies may apply a modified approach to the current unique identifier principles to confirm the identity of the drugs being imported. This would include:
        - visual inspection of the labelling on samples of product taken from each batch received against approved product labelling
        - visual comparison of the drug in dosage form against that of previously retained samples or other comparative information
        - application of physical measurements (e.g. dimensions, volume, etc.) of a sample of the drug in dosage form.

    - Canadian importers will still be required to meet all product release requirements as stipulated in C.02.014 "Quality Control Department" of the Food and Drug Regulations and the applicable interpretations under GUI-0001 "Good manufacturing practices guide for drug products." To this effect, it is important that Canadian importers have full traceability with respect to the manufacturer of the drug and associated supply/transportation chain. All companies conducting licensable activities for the product being released must have a Drug Establishment Licence (DEL) or be listed on the foreign site annex of the importer's DEL.

2. **Allowance for Shipping of Product from the Fabricator to Canada in Quarantine:** Health Canada is also aware of challenges associated with the transportation of drugs from other jurisdictions into Canada. Health Canada will, therefore, not object to product being shipped to Canada prior to the completion of all testing and fabricator release (i.e. ship in quarantine). Canadian importers are, as per current requirements, still expected to:
    - Have appropriate systems to quarantine all such incoming shipments until release. The quarantine system must effectively prevent the accidental shipment or release of such product.
    - Ensure all required testing is completed before such product is released to the Canadian market
    - Assess the product per all release requirements including an assessment of all testing certificates of analysis.

3. **Defer Confirmatory Testing When Required:** Health Canada is aware that importers have expressed concerns about being able to meet confirmatory testing requirements. Health Canada will accept deferment of confirmatory testing requirements if companies are not able to conduct such tests. Health Canada would like to remind importers that, per GUI-0001 "Good manufacturing practices guide for drug products" requirements, product may be

released for sale before the completion of confirmatory testing provided all other product release requirements are met.

Health Canada would like to stress that it remains the responsibility of the Canadian Quality Control department to ensure all product complies with Canadian regulations and marketing authorizations. It is expected that Canadian importers maintain appropriate oversight of their supplier and appropriately manage any identified risks. This includes a review of the supplier history to demonstrate they can consistently supply product that meets requirements if adopting the approaches outlined above.

Health Canada acknowledges that companies may experience challenges as a result of the COVID-19 pandemic. Responses to theses challenges should be based on an appropriately documented quality risk assessments and/or in accordance with your firm's pharmaceutical quality system requirements.

You may email hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca for further clarification on this interim approach.

DEL Bulletin LEEP No. 77 Health Canada Alleviates Confirmatory and Identity Testing Requirements for Certain Low Risk Non-prescription Drugs

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. Health Canada had previously outlined a new interim approach to prevent delays in the release of drugs to the Canadian market after importation into Canada from non-MRA countries per DEL Bulletin 76. This DEL Bulletin has been issued to expand upon DEL Bulletin 76 by introducing further measures in relation to low risk products. The measures will continue to ensure that medications sold in Canada continue to have appropriate drug quality oversight.

Effective immediately, for all importers of non-prescription drugs listed in Annex A that are being imported from a building subject to oversight by a PIC/S participating authority listed in Annex B (referred to as impacted products in the remainder the bulletin):

1. Identity testing will no longer be required after receipt in Canada as part of the release process, and

2. Confirmatory testing will also no longer be required.

Importers of impacted product must ensure that product meets specifications and were manufactured in accordance with the master production documents prior to releasing product for sale (please refer to GUI-0001 "Good manufacturing practices guide for drug products" for additional information).

Further to these requirements, importers of impacted product will also be given the option to directly ship (e.g. ship from a foreign fabricator directly to a retailer) on the condition that:

- The importer will release the drug before it is shipped by reviewing all applicable documentation and testing results;
- The importer will have measures in place to ensure all requirements of the regulations are met. This means identifying roles and responsibilities and having appropriate quality agreements between all parties including the foreign manufacturer, importer and person receiving the product (i.e. the retailer in the example provided above).

Health Canada would like to stress that it remains the responsibility of the Canadian Quality Control department to ensure all product complies with Canadian regulations. It is expected that Canadian importers maintain appropriate oversight of their supplier and appropriately manage any identified risks.

You may email hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca for further clarification on this interim approach.

DEL Bulletin

DEL Bulletin LEPP No. 78 Health Product Inspections and Licensing Blog

In 2018, Health Canada launched the Health Product Inspection and Licensing blog on the GC Collab platform. GC Collab is a professional collaboration platform, connecting public servants from across Canada with external stakeholders such as DEL holders. With multiple and important Inspection and Licensing communications of late, the blog serves as a convenient place to find current and past editions of these Bulletins.

The blog is updated every time a new DEL Bulletin or notice to stakeholders is issued and stakeholders receive notification of the posting. Moving forward towards using the blog as the source of DEL Bulletins will provide you with greater access and convenience to important information from Health Canada. As such, Health Canada is requesting that all stakeholders including DEL holders register for an account on the blog.

How to register for an account on GCcollab

- If you already receive the DEL Bulletins, an invitation link will be sent to you following this bulletin. Simply click the link and create a profile for GCCollab

- If you are not a recipient of the Bulletins, you can request to be added to the blog by emailing hc.del.questions-leppp.sc@canada.ca

Should you have any questions regarding this Bulletin, please contact the DEL Unit at: hc.del.questions-leppp.sc@canada.ca

DEL Bulletin LEPP No. 79 Information to Market Authorization Holders (MAHs) of Human Pharmaceutical Products Regarding Nitrosamine Impurities

Please note that this communication is intended for MAHs of human pharmaceutical products and over the counter medications. It is not intended for MAHs of biologics, radiopharmaceuticals, disinfectants, veterinary or natural health products.)

Background

As part of Health Canada's efforts to mitigate the risk of nitrosamine contamination for all active pharmaceutical ingredients (APIs) and drug products, Health Canada requested in its letter of October 2, 2019, that MAHs follow a three- step process for conducting risk assessments of their drug products containing chemically synthesized APIs. It was recognized that the volume of products to which this applies might be significant for some MAHs. Therefore, Health Canada requested that the risk assessments (Step 1) be conducted within 6 months of the issuance of the Health Canada October 2nd letter (i.e., by April 2, 2020).

Further, Health Canada requested that subsequent actions for confirmatory testing (Step 2) and any changes to the marketing authorizations (Step 3), as required, be completed within two years of the issuance of the Health Canada October 2nd letter (i.e., by October 1, 2021).

However, Health Canada is aware that due to the impact of the global outbreak of COVID-19 many MAHs are encountering significant challenges in completing the required nitrosamine impurities risk assessments and any necessary subsequent actions within the previously requested timeframes.

Extensions to the Deadlines - Conduct of the Risk Assessments and Subsequent Actions

As a result of the challenges related to the current COVID-19 situation, Health Canada is granting an extension as follows:

Step 1 – Risk Assessments:

- to be completed by October 1, 2020

Step 2 – Confirmatory Testing and Step 3 – Changes to the Market Authorization (as required):

- to be completed by October 1, 2022

Any additional questions relating to the original October 2, 2019 letter or this communication should be directed to hc.bps.enquiries.sc@canada.ca

Update to Health Canada's COVID-19 websites

Health Canada would like to inform you of the latest updates to the COVID-19 website, and invite you to share them through your networks.

First of all, Health Canada now has a specific page on disinfectants and hand sanitizers. From this page, Health Canada has access to the list of disinfectants and the list of hand sanitizers approved by Health Canada in the current context.

Hard Surface Disinfectants and Hand Sanitizers

https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19.html

Health Canada have also added a new page that includes all the necessary information required for industries, including the measures put in place to maximize access to these products in Canada. There are details on:

- published guidance on Health Canada's interim expedited licensing approach for the production and distribution of alcohol-based hand sanitizers
- process to facilitate importation of a hand sanitizers that have been authorized or registered in another country with a similar regulatory framework and quality assurance controls
- temporary flexibility related to distribution of hand sanitizers to hospitals and clinics
- the temporary flexibility allowing pharmacists to compound and sell hand sanitizers
- information on disinfectant claims for COVID-19, and
- the Hand Sanitizer Manufacturing Exchange managed by various industry associations

You can find other updates surrounding COVID-19 in the websites listed below:

COVID-19 Landing page:

https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html

Health product industry page:

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry.html

Diagnostic devices:

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19.html

Disinfectants:

https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19.html

If you have questions about the measures put in place by Health Canada to maximize access to disinfectants and hand sanitizers, please contact us at: hc.nnhpd-dpsnso.sc@canada.ca

Consumer and Hazardous Products Safety Directorate of Health Canada provides this clarification on the classification of hand sanitizers

Products represented to be “hand sanitizers” do not meet the definition of a cosmetic under the *Food and Drugs Act*. Antiseptic skin cleansers, including hand sanitizers, are considered to be natural health products or drugs, depending on their composition. Like other non-prescription drugs or natural health products, they are subject to the *Food and Drug Regulations* or the *Natural Health Products Regulations* administered by the Natural and Non-prescription Health Products Directorate (NNHPD).

Health Canada has compiled and published a list of antiseptic/antibacterial skin cleansers or hand sanitizers that meet Health Canada's requirements for safety, effectiveness and quality.

https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/hand-sanitizer.html

Further guidance about regulations for hand sanitizers is available here:

https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/human-use-antiseptic-drugs.html#a31

For more information on Health Canada's regulatory approach for hand sanitizers, please contact the Natural and Non-prescription Health Products Directorate at hc.nnhpd-dpsnso.sc@canada.ca.

An important ePost Connect Message from NNHPD

In light of recommendations by the Public Health Agency of Canada, as well as provincial, territorial and municipal measures aimed at slowing the spread of the COVID-19 virus, the NNHPD recognizes that companies with open product authorization applications may be experiencing business disruptions at this time. The NNHPD recognizes that for security or logistical reasons, the flow of information to Health Canada may be limited from some industry partners and applicants. To this effect, the NNHPD will consider providing flexibilities to companies with open product authorization requests with upcoming deadlines, in order to minimize refusals due to late responses, due to the COVID-19 outbreak. Please contact your submission coordinator identified in the notice, to inform the NNHPD, if you anticipate not being able to meet the expected standards outlined in this Information Request Notice.

Furthermore, please note that NNHPD staff are prioritizing and working to expedite applications related to the COVID-19 response. As such, this could result in the issuance of regulatory decisions for requests unrelated to COVID-19, outside of NNHPD’s published service standards. During this time, please do not email the NNHPD for status update requests for submissions and previously submitted inquiries.

Annual Compliance and Enforcement Report Fiscal Year: 2018-2019

The Consumer Product Safety Program (CPSP) is responsible for the administration and enforcement of the Canada Consumer Product Safety Act (CCPSA), and regulations made

under it, as well as cosmetic-related provisions of the Food and Drugs Act (FDA) and the Cosmetic Regulations.

Health Canada promotes, monitors, verifies, and enforces compliance with the CCPSA and the FDA. CPSP reviews reports submitted by industry and consumers and regularly monitors the marketplace to look for potentially dangerous products. CPSP gathers information, both domestically and internationally, about injuries, emerging issues and new science related to consumer product safety.

Annual Compliance and Enforcement Report

Mandatory Reporting Requirements during the COVID-19 Pandemic

COVID-19 is a rapidly evolving global issue. The Government of Canada will do everything necessary to protect the health, safety, and wellbeing of Canadians, and is working around the clock to limit the spread of this pandemic. Health Canada's top priority remains the safety and security of all Canadians.

Health Canada has been working closely with the Public Health Agency of Canada, which is leading the public health response and pandemic planning, as well as with provincial, territorial and international partners to respond to this evolving situation.

In light of the COVID-19 outbreak, Health Canada is clarifying expectations for manufacturers, importers and market authorization holders (MAHs) regarding requirement to report adverse reactions (ARs) and medical device problems (MDPs) during a pandemic.

Health Canada's Canada Vigilance Program collects and assesses reports of adverse reactions (ARs) to health products and medical device problems (MDPs). Manufacturers, importers and MAHs are required to report ARs and MDPs that come to their attention. During the COVID-19 pandemic, the Department will continue to use the existing Canada Vigilance as well as medical device incident databases to monitor and analyze adverse events to health products**.** Subsets of these databases are available online for ARs and MDIs.

Although every AR and MDP report is important, reporting ARs and MDPs within the regulatory timeframes may not be feasible due to the impact of the COVID-19 pandemic on normal business operations and personnel.

Regulatory reporting of ARs and MDPs should be maintained to the maximum extent possible. However, due to pandemic-related employee and personnel shortages, Health Canada accepts if the submission of AR and MDP reports to Health Canada does not occur within the time frames stipulated under various applicable regulations, provided that any delayed submissions are sent as soon as feasible. MAHs, manufacturers and importers should maintain records to identify what has been delayed.

Reporting expectations and timelines will be maintained for some high priority products or those that may be used in a pandemic. These include antivirals, vaccines, medicines for outbreak symptom management, medical devices for the diagnosis and management of patients with COVID-19, blood and blood components, cells, tissues and organs (CTOs) and drug identification number-assigned (DIN) manufactured blood products. Furthermore, reports with death as an outcome should also be treated as priority.

AR reports associated with COVID-19 should be identified as priority and submitted in the same manner as reports to Health Canada requiring expedited reporting timeframes, in accordance with the *Food and Drug Regulations*, *Natural Health Products Regulations, the Blood Regulations and the Cells, Tissues and Organs Regulations.* Medical device incidents associated with COVID-19 should be reported in accordance with Health Canada's Interim order respecting the importation and sale of medical devices for use in relation to COVID-19.

With respect to reporting methods, Health Canada is aware that manufacturers, importers and MAHs' ability to fax or mail reports may be affected by the current pandemic. In order to provide reporters with some flexibility surrounding the submission of AR and MDP reports, MAHs who are not currently enrolled as trading partners with Health Canada may submit reports using the online reporting application available on Health Canada's website. Key data elements and pieces of information captured in the Mandatory Adverse Reaction Form for Industry or Council for International Organizations of Medical Sciences (CIOMS) form should be incorporated into the online submission under the most appropriate fields.This is only an interim solution and usual reporting processes should be restored as soon as feasible. MDPs (Medical Device Problem Reporting Form for Industry) may continue to be submitted via email to hc.mdpr-dimm.sc@canada.ca.

Manufacturers, importers and MAHs as defined in the applicable Regulations should develop a business continuity plan (BCP) that outlines and justifies actions taken relating to AR or MDP reporting that differ from the requirements of the Regulations. As the pandemic progresses, the BCP should be maintained and updated as necessary.

Small Business Application Process Now Live

Health Canada wishes to inform you that the Drug and Medical Device Small Business Application is now live.

Information on the small business application process and a link to the Drug and Medical Device Small Business Application are now found on the Funding and Fees webpage.

If you have any questions, please contact us at hc.sbo-bpe.sc@canada.ca

Cost Recovery Reminder to Stakeholders

CA wishes to reminder stakeholders that the new Cost Recovery framework becomes effective April 1, 2020.

As of this date, there are new fees for human drugs, medical devices and veterinary products. The fee lines for these products include submission fees, facility licensing fees, right-to-sell fees and small business mitigation strategies.

Health Canada has updated their Funding and Fees website today which is located here https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees.html

If you have any questions on the new Funding and Fees, please reach out to your Cosmetics Alliance Regulatory Team at regulatory@cosmeticsalliance.ca.

Environmental Updates

Extension for Draft Science Assessment of Plastic Pollution

The Public Comment Period for the Draft Science Assessment of Plastic Pollution has been extended by 30 days. Stakeholders are invited to submit comments until May 1, 2020.

Effect of Coronavirus on Service Delivery – ECCC

Due to the situation with coronavirus (COVID-19), the program is adapting and is asking for your kind cooperation to ensure that quality and timely services continued to be delivered, wherever possible:

1-. New Substances Notification (NSN)
Effective upon receipt of this letter, please submit a notification using Environment and Climate Change Canada's Single Window (SWIM) or by e-mail (eccc.substances.eccc@canada.ca).

2-. Information Requests
For any requests, please continue using the Management Information Line either by phone (1-800-567-1999 (toll-free in Canada) or 819-938-3232) or by email (eccc.substances.eccc@canada.ca). Health Canada will respond to your requests as quickly as possible.

3-. Payments
At this time, payments cannot be processed immediately upon acknowledgement of receipt of notification packages. However, payments will be processed at a later date, in communication to the company. Evaluation of files will continue regardless of the payment processing delays. The Fee Payment Line will not be available in the coming weeks.

4-. Public comments
Please continue to use SWIM as mentioned in the publication notice and you can email your questions to (eccc.substances.eccc@canada.ca).

Post-Consumer Waste Updates

COVID-19 Could Disrupt Flow of Waste

For Ontario, roughly one-third of the Province's waste disposal needs are met by landfills in the United States. Please click below to see how COVID-19 can disrupt the flow of waste. Read more here.

Other Updates

Safety Assessor Training Video

The Gemran Cosmetic, Toiletry, Perfumery and Detergent Asscoation has developped trainings for safety assessors in cooperation with the German society of cosmetic chemists in Germany (DGK). These 7 trainings are available in English and can also be booked online as webinars. All details about the trainings can be found here:

https://www.safetyassessor.info/trainingswebinars.html

Some attendees have asked for further details on the trainings. Below is a short video in which the concept is explained in more detail.

https://www.ikw.org/fileadmin/ikw/downloads/Schoenheitspflege/2020_DGK_IKW_Webinars_-_Introduction.mp4

For more information please email Bhuber@ikw.org or please vist www.ikw.org.

Introduction to the Canadian Code of Advertising Standards & Consumer Complaints Procedure

Ad Standards is pleased to present an introduction to the *Canadian Code of Advertising Standards* (*Code*), Canada's principal instrument of advertising regulation. It sets out the standards for acceptable advertising and provides a mechanism for Ad Standards to review and adjudicate complaints from the public and advertiser disputes. Essential for those new to the industry or a refresher for those with experience, this 1-hour practical session will illustrate how the *Code's* key clauses are applied in the context of the 2019 Ad Complaints Report (coming soon).

Due to the recent social distancing imperative, Ad Standards has made the decision to transition the upcoming Intro to the *Canadian Code of Advertising Standards* seminars from live formats to an online Webinar. The previously scheduled seminars, in Toronto (April 20) and Montreal (April 22), have been cancelled.

The Webinar will take place on Monday, April 20 from 10 to 11 a.m and will cover the same material as the live versions. You can read the full event description at the registration link below.

Date:
Monday, April 20, 2020

Time: 10:00 a.m. to 11:00 a.m.

Cost:

Non-Members: $20 plus HST

Members: Free of charge

Register