Regulatory Essentials – March 17, 2021

Cosmetics Alliance Updates

Save the Date for CA's First Ever Virtual Spring Regulatory Workshop!

Save the Date for our first ever virtual Regulatory Workshop on June 1st – 2nd, 2021. Cosmetic Alliance Regulatory Workshop provides members with the opportunity to stay up-to-date and informed on "everything regulatory". Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business. You also do not want to miss the Member Engagement Session the next day to discuss what was heard the day before with your industry colleagues and CA Staff.

You do not want to miss this event! Mark your calendars now, registration will open soon. Price of the workshop is per login; attendees can not share logins.

Regulatory Workshop Details:

Date: June 1st, 2021

Time: 13:00 – 16:00 EST

Location: Virtual

Price: $350 (incl. Member Engagement Session)

Member Engagement Session:

Date: June 2nd, 2021

Time: 13:00 - 14:30 EST

Location: Virtual

Webinar - The State of Canada's Beauty Market and 2021 Outlook

Date: Thursday, March 25, 2021

Time: 2:00 pm - 2:45 pm EDT

Cost: Member: Free Non-Member: $50

The NPD Group's Alecsandra Hancas, Canadian Beauty Industry Analyst, will share our annual State of the Canadian Beauty Market insights. She'll also explore trends that shaped the Beauty Industry in 2020, including consumers' rising interest in skincare and "feel good" beauty. You'll hear insights on how Canada's lockdowns and work-from-home shift altered consumers' needs in 2020 and get Alecsandra's take on the trends we expect to continue in this year.

Register

Health Updates

Important Message - Drug Establishment Licenses for DIN Hand Sanitizers

The *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* included a flexibility to conduct licensable activities (fabrication, packaging, labelling, importation, testing and distribution) for DIN Hand Sanitizers without a requirements for a Drug Establishment Licence (DEL). This flexibility is being lifted as of September 1st, 2021.

A six-month transition is being given to allow industry to adjust to the elimination of this flexibility.

This six-month transition period is from March 1st to September 1st, 2021.

During this transition period, you may continue to conduct these activities without a DEL until September 1st, 2021.

During this transition period you can apply for a DEL (or amend your DEL) if you wish to continue conducting the activities beyond September 1st, 2021.

If you do not wish to continue conduction these activities post September 1st, 2021 you need not apply.

Importers and sellers of DIN Hand Sanitizers remain responsible for ensuring they meet all applicable Good Manufacturing Practices (GMPs) under the Food and Drug Regulations before, during and after the transition period.

The application for a DEL during the transition period continues to follow the requirements of the:

- *Guidance on Drug Establishment Licences (GUI-0002)* and
- *Management of Applications and Performance for Drug Establishment Licences (GUI-0127)* and
- *How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)*.

The following information should also be included in your application package:

- written indication in the body of the application email or cover letter that the DEL application is related to activities conducted for a hand sanitizer while the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19 was in effect.
- name of the specific hand sanitizer product(s) for which licensable activities were conducted.

Once your application has been submitted you need to be ready for an inspection (audit) by Health Canada prior to the issuance of the Drug Establishment Licence.

For questions on the DEL transition period or application requirements, please contact hc.del.questions-leppp.sc@canada.ca.

For questions on GMP requirements, please contact hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca indicating "COVID-19" in the email subject line".

GUI - 0104 EN/FR

GUI - 0104 Comment Form – EN/FR

Natural Health Products Site Form Feedback

The Natural and Non-prescription Health Products Directorate (NNHPD) is seeking feedback on the new web-based harmonized site licence and foreign site reference number (FSRN) application form (web SLA). The form was released this past November and has enabled the NNHPD to go paperless.

Cosmetics Alliance will be working with our Facility Compliance & Manufacturing Committee to consolidate feedback on the Site Form.

While some feedback has been received, NNHPD would like to learn more about how the form is working and what could be improved. Please provide your response to hc.nnhpd.consultation-dpsnso.sc@canada.ca by Wednesday, **March 31, 2021**.

Site Licence Feedback Form – EN/FR

Your Input Please - Submission Review Concerns for Upcoming Performance Standards Call for NHP applications

In preparation for the upcoming meeting on March 24, 2021 from 2:00 - 3:00pm EDT titled "Performance standards for NHP applications", please find below the proposed agenda.

- Workload update: Product and Site licence applications (30 minutes)
- Discussion on submission related issues (15 minutes)

- Systems update (15 minutes)

As a result of the Agenda Item proposed by Cosmetics Alliance during the Multilateral Meeting held on February 24th, around concerns regarding the submission review experience, NNHPD invites you to share some examples of your experience where the communication approach was found to be insufficient or lacking (and why). Please provide any examples to Karen.french@canada.ca by no later than March 19th.

Teleconference details are available below:

Toll-Free: 1 855-288-0982
Local: 1-438-797-4001
Conference ID: 173 468 7729

Regulatory Enrollment Process (REP) Update

Cosmetics Alliance has been working with Health Canada officials in the Office of Submissions and Intellectual Property (OSIP) to develop an information package for our membership on the use of the REP to provide:

- a summary of the REP
- a consolidation of the guidance documents
- the use of the Common Electronics Submission Gateway (CESG) and
- interim frequently asked questions/commonly encountered mistakes until a revised FAQ document has been issued.

As you know, as of October 1, 2020, the REP became a mandatory filing requirement applicable to **all pharmaceutical**, biologic and radiopharmaceutical drugs for human use as well as disinfectants, pursuant to Part C, **Division 1** and **Division 8** of the Food and Drug Regulations.

The REP replaces the processes for the existing Health Canada 3011: Drug Submission Application Form *and* the Drug Submission - Application Fee Form for Human and Disinfectant Drugs.

Please refer to the notice for more information.

From the REP information page, you can access the link to the template, stylesheets, dossier ID request form and video tutorials.

The following guidance documents which are only available from Health Canada by sending an e-mail to them are available on the Cosmetics Alliance.

- Common Electronic Submissions Gateway (CESG) Health Canada Reference Guide
- Guidance Document: The Regulatory Enrolment Process (REP)
- Frequently Asked Questions (FAQ) Document (Oct 2020)
- Third Party Authorization Sample Template

The REP Guidance Document should always be the main reference.

Those stakeholders using e-CTD are referred to the following information here.

Cosmetics Alliance has also been working with OSIP to develop a document listing of some of the more common mistakes manufacturers have made when using REP that results in processing delays and in some cases rejected transactions. This information will be incorporated into the next version of the FAQ.

Based on the internal and external feedback received thus far, improvements to the templates, clarification in the instructions and revisions to the guidance document will be available soon.

If you have any questions regarding REP please email hc.ereview.sc@canada.ca.

In addition, the payment procedures are outlined in the How to Pay Fees for Health Products Website and you can also refer to the Guidance document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications for more information.

Nitrosamines as Impurities in Drugs; Health Risk Assessment and Mitigation Public Workshop - 03/29/2021 - 03/30/2021

The Food & Drugs Administration is hosting a public workshop on Nitrosamines as Impurities in Drugs. The workshop will include presentations on nitrosamines chemistry and toxicology and, on the finding of nitrosamines as impurities in drugs. The presentations will be followed by open discussion of questions prepared by the FDA and presented to expert panelists for deliberations over 2 days. Topics to be addressed include nitrosamines as chemicals present in the environment, in food and, more recently, detected as impurities in drugs, nitrosamine pharmacokinetics, carcinogenesis, mutagenesis, (Q)SAR, and health risk assessment and mitigation. In addition, the panelists will be asked to identify data gaps and research needs to address uncertainties in nitrosamine safety assessment and how to prevent or minimize their presence in drugs.

More Information & Registration

Updates to Monographs for web PLA form

Over the course of March 2021, the Natural and Non-prescription Health Product Directorate will be updating monographs to support validation within version 4 of the web-based product licence application form. Changes to the monographs **do not affect already approved products** and correcting issues with certain product types to enable monograph quicker monograph applications.

Please find below a summary of the monograph revisions to be posted:

1) Sage – Buccal; Rosemary – Topical; Althaea Officinalis – Leaf; Althaea Officinalis – Root; and Bilberry – Buccal: Revisions to the methods of preparation and directions for use.

2) Arnica: Addition of missing extract information.

3) Benzocaine:
    - Addition of Table 1 (proper name, common name and source information)
    - Addition of a list of acceptable dosage forms rather than unacceptable ones: Aerosol, spray; Cream; Film-forming gel; Gargle; Gel; Gingival gel; Gingival paste; Liquid; Lozenge (oral only); Mouthwash; Ointment; Solution; Spray.
    - Addition of 2 routes of administration: Gingival and Oromucosal
    - Revision to associations between dosage forms and subpopulations.
    - Reorganization of Directions of use and risk statements by claim and/or dosage forms
    - Revision to storage conditions to indicate a temperature that would be appropriate for all products.

4) Cayenne – Capsicum annuum/capsaicin topical:
    - Addition of capsaicin as medicinal ingredient.
    - Restriction of the dosage forms to Cream; Fluid extract; Gel; Liniment; Liquid; Lotion; Oil; Ointment; Salve; Solution; Tincture; Topical liquid.
    - Removal of the term “Traditional” from the herbal medicine claim and revised to ‘Used in Herbal Medicine’ as only standardized preparations are included in the monograph.
    - Revision to the dose information for the Herbal Medicine claim from 20-70 mg of dried fruits to a concentration of capsaicinoids in the finished product, based on BHP 1983.

5) Traditional Chinese Medicine Ingredients:
    - Addition of a footnote to table 1 under the quantity section to make the following statement more visible: “Products providing more than 1 g of Piper longum are excluded from this monograph”.
    - Addition of example risk statements that would be required based on other reference texts.
    - Inclusion/revision of some of the medicinal ingredients to ensure consistency between the monograph and Natural Health Products Ingredients Database.

6) Cognitive Function Monograph:
    - Updates to methods of preparation for Panax quinquefolius, Anemone pulsatilla, Valeriana officinalis, Hypericum perforatum, Bacopa monnieri, Ginkgo biloba, Rhodiola rosea, Ilex paraguariensis, Ganoderma lucidum, Glycyrrhiza glabra, Panax ginseng, and Tinospora cordifolia.
    - Addition of common names for ilex paraguariensis
    - Revision to source material and part for Gama-Aminobutyric acid from Laminaria japonica to Lactobacillus hilgardii – Whole cell for biosynthesis
    - Revised source parts for Eleutherococcus senticosus, Panax quinquefolius, Tinospora cordifolia and Withania somnifera.

- Revision to traditional claims parameters.
- French monograph: Revision to dosing information for Panax ginseng to match English version.

If you have any questions please contact Alysyn Smith (alysyn.smith@canada.ca).

Health Canada's 2020 Virtual Stakeholder Meeting on Health Products

The Health Product and Food Branch shared their summary report from the Virtual Stakeholder Meeting on Health Products, which took place on December 4, 2020.

Cosmetics Alliance's Darren Praznik, Beta Montemayor, Richard Parcels and Linitha Ganesh attend the meeting which focused on Health Canada's response to the COVID-19 pandemic and their plans for regulatory modernization as they build on the lessons learned from this experience.

Drug Submission Performance Quarterly Reports (October-December 2020)

The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of the pre-market drug review process against performance service standards. The quarterly report compares five consecutive quarters from October-December 2019 to October-December 2020. The reports are broken down by operational areas.

TPD – EN/FR

NNHPD – EN/FR

BRDD – EN/FR

Environmental Updates

Various Publications Under the Chemicals Management Plan

Hexamethylenetetramines Group

The draft screening assessment and risk management scope for the Hexamethylenetetramines Group was published for a 60-day public comment period ending on May 5, 2021. The substances under the DSA are:

CAS RN	Common name	DSL name
4080-31-3 [a]	Quaternium-15 [b] Cis/trans-CTAC	3,5,7-Triaza-1-azoniatricyclo [3.3.1.1³,7]decane, 1-(3-chloro-2-propenyl)-, chloride
51229-78-8 [c]	Quaternium-15 [d] Cis-CTAC	3,5,7-Triaza-1-azoniatricyclo [3.3.1.1³,7]decane, 1-(3-chloro-2-propenyl)-, chloride, (Z)-
58713-21-6 [c]	Methenamine hydrochloride	1,3,5,7-Tetraazatricyclo [3.3.1.1³,7]decane, hydrochloride

It is proposed to conclude that methenamine hydrochloride does not meet any of the criteria set out in section 64 of the CEPA

And whereas it is proposed to conclude that cis/trans-CTAC and cis-CTAC meet one or more of the criteria set out in section 64 of the Act, and will be recommended to be added to Schedule 1 of CEPA. Notice is furthermore given that the ministers have released a risk management scope document for these substances to initiate discussions with stakeholders on the development of risk management options. Cosmetics Alliance will not be providing feedback on the DSAR unless interest is shown by members. If you would like CA to provide comments on the FSAR please email regulatory@cosmeticsalliance.caThe final screening assessment is proposed to be released in March 2022.

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/hexamethylenetetramines-group.html

Chlorhexidine and its salts

The proposed order adding Chlorhexidine and its salts to Schedule 1 of the Canadian Environmental Protection Act, 1999 was published for a 60-day public comment period ending on May 5, 2021. Chlorhexidine and its salts meet the ecological criterion for a toxic substance, as set out in paragraph 64 of CEPA. Therefore, in accordance with subsection 90(1) of CEPA, the Minister of the Environment and the Minister of Health are recommending to the Administrator in Council to make an order adding chlorhexidine and its salts to Schedule 1 of CEPA. The conclusions for this assessment are considered to cover chlorhexidine and its salts, which include, but are not limited to, the four substances below.

CAS RN [a]	Common name	DSL [b] name or chemical name
55-56-1	Chlorhexidine	2,4,11,13-Tetraazatetradecanediimidamide, *N*,*N*''-bis(4-chlorophenyl)-3,12-diimino-
56-95-1	Chlorhexidine diacetate	2,4,11,13-Tetraazatetradecanediimidamide, *N*,*N*''-bis(4-chlorophenyl)-3,12-diimino-, diacetate
3697-42-5	Chlorhexidine dihydrochloride	2,4,11,13-Tetraazatetradecanediimidamide, *N*,*N*''-bis(4-chlorophenyl)-3,12-diimino-, dihydrochloride
18472-51-0	Chlorhexidine digluconate	D-Gluconic acid, compound with *N*,*N*''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide

The Draft Screening Assessment was released on August 19, 2017 with the final screening assessment released on June 29, 2019. Cosmetics Alliance did not engage in the public comment period for the DSAR or FSAR as interest was not shown by membership.

https://www.canada.ca/en/health-canada/services/chemical-substances/other-chemical-substances-interest/chlorhexidine-salts.html

Ethers Group

The Draft Screening Assessment for the Ethers Group was published for a 60-day public comment period ending on May 12, 2021. The substances in the DSAR are:

Substance group	CAS RN	Common name and acronym	DSL name	Draft screening assessment	Proposed conclusion on section 64 criteria	Follow-up activities
Ethers Group	60-29-7	Diethyl ether (DEE)	Ethane, 1,1'-oxybis-	HTML	Does not meet	None planned at this time
	101-84-8	Diphenyl ether (DPE)	Benzene, 1,1'-oxybis-			
	115-10-6 [a]	Dimethyl ether (DME)	Methane, oxybis-			
	34590-94-8	Dipropylene glycol methyl ether (DPGME)	Propanol, 1(or 2) -(2-methoxymethylethoxy)-			

The substances have been concluded to not meet any of the criteria set out in Section 64 of CEPA. Cosmetics Alliance will not be engaging in the public comment period unless interest is shown by members. If you would like CA to provide comments on the DSAR please email regulatory@cosmeticsalliance.ca. The Final Screening Assessment is anticipated to be released in March 2022.

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/ethers-group.html

Post-Consumer Waste Updates

Canadian Stewardship Services Alliance Joins Canada Plastics Pact

Canadian Stewardship Services Alliance Inc. recently joined with more than 40 organizations to launch the Canada Plastics Pact (CPP) and work collectively to end plastic waste and pollution. The CPP unites businesses, government, non-governmental organizations, and other key actors in the local plastics value chain to fundamentally rethink the way they design, use, and reuse plastic packaging. More information is available here.