Regulatory Essentials – September 30, 2020

Cosmetics Alliance Updates

Second Series Continuing the Focus on Natural Health Products

CA is offering another set of interactive training sessions. These next sessions will focus on Natural Health Product Labelling, Site Licensing and Good Manufacturing Practices. Save 25% when you register for all three training sessions at the same time.

Take advantage of our special pricing when you register for all three.

Natural Health Product Labelling

Date: Wednesday, September 30, 2020

Time: 2:00 pm - 3:30 pm

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

Learn and Understand:

- What information you need to place on your label and where
- How to navigate the advertising and labelling claims guidance documents
- What the variable pieces of information on a label are

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

Free E-commerce Webinar with Dragon's Den Michele Romanow - Your Direct to Consumer Questions Answered by Experts

Event Details:

Thursday October 1st, 2020

2pm-3pm

Discussion Points:

- What is the current state of e-commerce?
- What are brands doing right now in e-commerce?
- What does it take for brands companies to be successful in the e-commerce space?

Presenters:

1. Michele Romanow
   Co-Founder/President - Clearbanc

Dragon - Dragon's Den

2. Kris Calder
   Founder - OrderGrid

Register Now - There is limited seating so register now while spaces are still available!

Health Updates

Rescheduled Health Canada Webinar - Packaging and Labeling Requirements for Alcohol-Based Hand Sanitizers

On Thursday October 1, Health Canada will be hosting a webinar to inform you of a policy change to reduce unintentional ingestion of alcohol-based sanitizers packaged in beverage containers. The high demand plus existing production capacity has led to significant product shortages in both products and standard packaging. Packaging shortages have resulted in the use of other unconventional types of containers such as beverage or drinking containers (for example, water and wine bottles).

The use of beverage containers for alcohol-based hand sanitizers may increase the risk of unintentional ingestion. Based on data from Canadian Poison Control Centres (PCCs), the number of reported incidents continues to increase in 2020 and is higher than in 2019.

To address this risk the Natural and Non-Prescription Health Products Directorate (NNHPD) will be implementing a policy requiring an alternative closure and an additional warning statement and symbol to alcohol-based hand sanitizers packaged in beverage containers.

Consultation on the draft policy took place from August 12, 2020, to September 2, 2020. NNHPD will be holding a call to provide a consultation summary on Monday, September 28, 2020, from 11:30-12:00pm EDT. Meeting details are available below.

Meeting number: 164 182 3811

Password: dqMtUrSs336

Meeting link: https://gts-ee.webex.com/gts-ee/j.php?MTID=m8f957ac3beabbe70c066eb85196eb561

Join by phone

Call-in toll-free number: 1-844-547-1539

Call-in number: 1-613-244-1321

Attendee access code: 886 420 1

DEL Bulletin LEPP No. 95 New pathway to expedite the authorization for importing, selling and advertising of COVID-19 drugs

The Interim Order introduces new regulatory mechanisms to expedite the authorization of COVID-19 drugs during a public health emergency, while still upholding the requirements necessary for the health and safety of Canadians.

The Interim Order does not apply to:

- non-prescription pharmaceuticals available over-the-counter
- disinfectants and hand sanitizers (antiseptic skin cleanser)
- veterinary health products
- natural health products as defined in subsection 1(1) of the Natural Health Products Regulations

The Interim Order applies to the following COVID-19 drugs:

- prescription and non-prescription professional use pharmaceuticals
- radiopharmaceuticals
- biologically-derived products such as vaccines, blood derived products, and products produced through biotechnology
- veterinary drugs

The Interim Order provides the Minister with the authority to permit the sale of a COVID-19 drug in Canada via three mechanisms.

1. authorizing a new COVID-19 indication for a new drug, or for one that holds an existing authorization or notice of compliance with a modified set of application requirements with the potential for a “rolling” submission of information
2. expanding an indication of a drug that is already licensed in Canada under the Food and Drug Regulations (Regulations), to include a COVID-19 indication based on known evidence and
3. authorizing a drug based on certain elements being authorized by a foreign regulatory authority

- The first mechanism is initiated by an application to Health Canada;
- the second mechanism is initiated by Health Canada (no application required); and
- the third mechanism is initiated by an application to Health Canada once Health Canada has added the drug to the List of Foreign Drugs.

Applicants can choose the appropriate regulatory pathway for market authorization:

- filing a submission and obtaining a notice of compliance under Division 8 of the Regulations or
- filing an application and obtaining an authorization under the Interim Order.

Applicants choosing to file under Division 8 of the Regulations should refer to the relevant guidance documents and fees applicable to that pathway.

This guidance document supports the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 supports the interim order and provides guidance to applicants seeking to have a COVID-19 drug authorized. It also sets out the conditions to be met after an authorization is granted under this interim order.

FAQ-IO Drug Authorization – EN
FAQ-IO Drug Authorization - FR

Validation rules for regulatory transactions in the “non-eCTD electronic-only" format

Health Canada has updated the validation rules for regulatory transactions submitted in the non-eCTD format. These rules are built in accordance with the information provided in the following documents:

- Guidance Document: Preparation of Regulatory Activities in “Non-eCTD Electronic-Only” format
- Guidance Document: The Regulatory Enrolment Process (REP)

The purpose of the validation rules is to help ensure Sponsors provide a valid electronic transaction to Health Canada, and reduce errors and follow-up with Sponsors. Sponsors are encouraged to use a commercially available tool to validate their regulatory transactions in non-eCTD format, prior to filing them 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.

Beginning November 1, 2020, Health Canada will be using the non-eCTD validation rules version 5.0.

Environmental Updates

Update on the Revised In-Commerce List (R-ICL)

The New Substances Assessment and Control Bureau released a notice today in CG1 related to the R-ICL with a 60-day comment period. This Canada Gazette Notice proposes de-listing certain substances from the R-ICL based on Health Canada records, and on information received following a mandatory survey pursuant to section 71 of CEPA that was published in the Canada Gazette, Part I, in January 2017, entitled *Notice with respect to substances included as part of the 2017 Inventory Update*. This mandatory survey included a subset of substances from the R-ICL in Part 4, Schedule 1 of the Canada Gazette Notice. Based on the available information, the substances proposed for de-listing were assumed to not currently be in Canadian commerce in products regulated under the *Food and Drugs Act* (F&DA), or to be potentially in use in such products at annual volumes below the triggers for notification of the *New Substances Notification Regulations (Chemicals & Polymers)* [NSNR(C&P)] of the *Canadian Environmental Protection Act*.

Cosmetics Alliance will be engaging in this consultation and will be working with its Risk Assessment and Ingredient Safety Committee to gain feedback and comments for this consultation. If you would like to join our committee and provide comments for this consultation please email regulatory@cosmeticsalliance.ca.

Canada Gazette Notice (Part I) - Notice of Intent to Remove Low Volume or Discontinued Substances from the Revised In Commerce List

http://www.gazette.gc.ca/rp-pr/p1/2020/2020-09-26/html/notice-avis-eng.html#na8

Consultation Document - Proposed Removal of Low Volume or Discontinued Substances from the Revised In Commerce List

https://www.canada.ca/en/environment-climate-change/services/managing-pollution/proposed-removal-low-volume-discontinued-substances-ricl.html

Webpage - Removal of substances from the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/removal-substances-revised-commerce-list.html

Webpage - Results of the prioritization of the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/results-prioritization-substances-revised-commerce-list.html

Webpage - About the Revised In Commerce List (R-ICL)

https://www.canada.ca/en/health-canada/services/environmental-workplace-health/environmental-contaminants/drugs-personal-care-products/environmental-impact-initiative/commerce-list-food-drugs-act-substances/revised-commerce-list-food-drugs-act-substances-health-canada-1.html

Webpage - Facts about the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/environmental-workplace-health/environmental-contaminants/drugs-personal-care-products/environmental-impact-initiative/commerce-list-food-drugs-act-substances/frequently-asked-questions-faqs-commerce-list-food-drugs-act-substances.html

Other Update

Ad Standards Code of Compliance Webinar

English Webinar - Register

Thursday, October 15, 2020

1:00 to 2:30 pm

Free for Members

$20 (plus tax) for Non-Members

French Webinar - Register

Thursday, October 22, 2020

1:00 to 2:30 pm

Free for Members

$20 (plus tax) for Non-Members

Ad Standards is pleased to present these *Code* Compliance webinars, which will help industry members better understand how the *Canadian Code of Advertising Standards* is applied. The sessions will include additional details on the findings of the 2019 Ad Complaints and Disputes Report, discuss the consumer complaints and advertiser dispute processes, and provide some insights about the types of complaints we are receiving about advertising related to the COVID-19 pandemic, how we handle them, and some practical tips to assist the advertising industry during the pandemic and beyond.

The English webinar will be presented by Catherine Bate, Chief Legal & Policy Officer; Leore Rosmarin, Legal Counsel; and Yamina Bennacer, Senior Manager, Standards.

Please note, the access info for the English Zoom Webinar will be shared with registrants via an Eventbrite email on Wednesday, October 14.