

Regulatory Essentials – June 10, 2020

Cosmetics Alliance Updates

Cosmetics Alliance Interactive Training Series

First Series Focused on NHP Market Access

CA's first series of interactive training sessions introduces natural health products (NHPs) and the regulatory requirements for market access.

Each of the individual sessions builds upon the previous one.

Product Licensing Overview

Date: Wednesday, June 10, 2020

Time: 2:00 pm - 3:30 pm

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

Learn and Understand:

- How to navigate the product licensing regulations
- The required elements of a product licence application
- The types of product licence applications available to applicants
- How Health Canada processes applications

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

How to Use the Web-Based e-Product Licence Application (PLA) Form

Date: Tuesday, June 23, 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 e-PLA
- How to navigate and use the e-PLA
- The resources available at Health Canada on using the e-PLA
- How to submit the e-PLA for gaining market access
- Where the e-PLA 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.

<https://myemail.constantcontact.com/Cosmetics-Alliance-Interactive-Training-Series-.html?soid=1102801646439&aid=X4oaYJ4EBQA>

Health Updates

Cosmetics Unit Temporary Staffing Changes

Emily Felisatti has recently accepted a 6-month assignment at PHAC starting June 1. In Emily's temporary absence Magdalena Jurkiewicz and Nibal Saikali have agreed to act as the Cosmetics Unit head. Magdalena will be acting from June 1 – September 4, 2020, and Nibal will be acting from September 7 – December 1, 2020.

UPDATE: Interim guide on the production of Isopropyl Alcohol (IPA) for use in alcohol-based hand sanitizers

Given the current demand for hand sanitizer in Canada and a shortage of ethanol, industry stakeholders have expressed a strong interest in using isopropyl alcohol (IPA) as the basis for hand sanitizer and have asked for guidance on acceptable grades.

Health Canada has just released their Interim Guide on the Production of IPA for use in Alcohol-Based Hand Sanitizers ([English](#) / [French](#)).

The Guide is intended to complement the [Guide on Health Canada's Interim Expedited Licensing Approach for the Production and Distribution of Alcohol-Based Hand Sanitizers](#).

Cosmetics Alliance worked closely with the NNHPD in developing this guide over the last number of weeks. It provides information regarding acceptable sources of IPA and guidance on quality requirements.

The guide outlines the requirements for alternate sources of IPA which are not any of the following standards:

- U.S. Pharmacopeia (USP)
- European Pharmacopeia (Ph. Eur.)
- Food Chemical Codex (FCC)
- British Pharmacopoeia (BP)
- Pharmacopée française (Ph.f.) (in french only)
- Pharmacopoeia Internationalis (Ph.I.)
- Japanese Pharmacopoeia (JP)
- National Formulary (NF)

Laboratory/electronic grade: Impurities are potentially undetected by food or drug analysis methods suited for human application and therefore laboratory/electronic grade IPA is not acceptable.

Technical grade: Only IPA that meets one of the above acceptable quality grades, is manufactured for human use as a food or drug, and has no other impurities outside of the limits established in the acceptable quality standards (including non-volatile residue introduced through the manufacturing process) is acceptable for use in hand sanitizers

Key Information: If you chose to use technical grade IPA in your product, you need to notify Health Canada of this decision via e-mail. There is no need to wait for approval.

Labelling requirements: There are no specific, additional labelling requirements for hand sanitizers containing IPA as any IPA (including technical grade) acceptable for use in hand sanitizers needs to meet or exceed the quality standards set out in this guide.

Health Canada's Drug and Medical Device Highlights 2019

Health Canada would like to share with you the link to the [Drug and Medical Device Annual Highlights 2019 Report](#). This is part of Health Canada's commitment to make more information available to patients, the public and our stakeholders.

This is the fifth annual report to be published. As with previous editions the 2019 Report covers product authorizations over the past calendar year, it also encapsulates two key themes: regulatory innovation and international collaboration. The report gives information about new drugs and medical devices that Health Canada approved for sale in Canada. Recent editions include information about potential safety issues, and an overview of the year's accomplishments related to drugs and medical devices.

Post-Consumer Waste Updates

Canadian Stewardship Services Alliance – Reporting Deadline Extension

Stewards are reminded that reports of PPP data may be submitted via the [WeRecycle Portal](#) up to July 31, 2020, rather than the regular May 31 deadline. The change was announced in early April to help businesses with their Packaging and Paper Product (PPP) obligations during this difficult time. Also, stewards unable to collect 2019 data have the option to reuse their 2018 data for the report, subject to [conditions and details](#). A range of [Reporting Resources](#) is available to guide stewards in collecting and reporting material data. Thanks to all stewards who have submitted reports and those who can do so before the deadline.