Regulatory Essentials – May 26, 2021

Cosmetics Alliance Updates

Virtual Spring Regulatory Workshop – Next Tuesday! – Register Today!

Get ready 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. Take part in our Member Engagement Session the next day to discuss what was heard the day before with your industry colleagues and CA Staff.

The regulatory workshop will also feature a new panel session with Health Canada's Director Generals:

Linsey Hollett – HPCD (ROEB)

Roger Charland - CHPSD

Natalie Page - NNHPD

along with CAC's President Darren Praznik.

This panel session will explore the future for the personal care product industry and how experiences over the last year can be leveraged in shaping the Self-Care Framework.

Do not miss out on this opportunity to engage with them and ask questions which matter to you.

Price of the workshop is per login; attendees can not share logins.

Final Workshop Agenda

Final Member Engagement Session Agenda

Regulatory Workshop Details

Date: June 1, 2021

Time: 9:00 a.m. - 12:00 p.m. EDT

Location: Virtual

Cost: $350 (including Member Engagement Session)

Member Engagement Session

Date: June 2, 2021

Time: 9:00 a.m. - 10:30 a.m. EDT

Location: Virtual

Register

Interactive Training Session: INCI - What's in a Name?

Date: Thursday, May 27, 2021

Time: 2:00 pm - 3:30 pm EDT

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

INCI nomenclature and the INCI registration process are important for stakeholders in the cosmetics industry to understand before selecting ingredients at the product development stage.

This interactive training session (which includes activities and a quiz) will help you learn and understand:

o The history of INCI

o The Canadian cosmetic ingredient labelling requirements (refresher)

o The International perspective

- Canada (CUSMA)
- European Union Cosmetic Ingredient Database (Coslng)

o How an INCI name is designated

- Application process
- INCI conventions
- Publication

o INCI name changes

- Implications in China

o wINCI and the InfoBase as resources

Presented by:

Joanne Nikitakis Sr. Director of Cosmetic Chemistry - Personal Care Products Council

Joanne Nikitakis is a member of the science team at the Personal Care Products Council as the Sr. Director of Cosmetic Chemistry. For more than 25 years, Joanne has been involved with the development of the INCI nomenclature program and publication of the International Cosmetic Ingredient Dictionary and Handbook in which she serves as principal editor. In her role, she serves as the staff liaison for the Council's Quality Assurance Committee and International Cosmetic Ingredient Nomenclature Committee, and provides technical support for activities associated with these Committees. Joanne has also served as editor of the Council's Quality Assurance Guidelines, and the Compendium of Cosmetic Ingredient Composition.

Ms. Nikitakis received her B.S. degree in Chemistry from the University of Mary Washington in Fredericksburg, Virginia, and M.S. in Pharmaceutical Sciences from the University of Cincinnati, College of Pharmacy in Cincinnati, Ohio.

Richard Parcels Assistant Director, Regulation & Market Access - Cosmetics Alliance Canada

Richard Parcels is the Assistant Director, Regulation & Market Access for Cosmetics Alliance Canada. He works to enhance and protect the ability of member companies to conduct business effectively in Canada by fostering industry and government cooperation and by using sound science and risk-based approaches to inform and shape regulation, policy and guidance.

Richard has over twenty years of experience in the pharmaceutical, natural health product, cosmetic and medical device fields. He obtained a B.Sc. in Microbiology from the University of Guelph and has previously worked at Agriculture Canada, Warner-Lambert Parke-Davis, AstraZeneca, Estee Lauder and as an industry consultant for 12 years. He specializes in regulatory affairs, quality systems, training and auditing.

Register

Health Updates

Quarterly Consumer Product and Cosmetic Reports Received Summary for Q4 2020-2021

The Consumer and Hazardous Products Safety Directorate regularly receives reports on human health or safety concerns related to consumer products and cosmetics. Consumer products are regulated under the *Canada Consumer Product Safety Act,* while cosmetics are covered under the *Food and Drugs Act*. The Reports Received by the Consumer and Hazardous Products Safety Directorate Quarterly Data January 1 to March 31, 2021 was recently published and the summary of the report is below.

Summary of the Report:

- 688: Number of reports received by the Consumer and Hazardous Products Safety Directorate.
- Cosmetics is one of the top five product types based on number of reports received
    - Second highest number of reports received
    - 29 reports received for cosmetics
- 271 reports received included an injury
- Top 3 injury types were irritation, burns and cuts

For the full report please click here.

DEL Bulletin LEPP No. 113 Requirements to notify or report to Health Canada-REMINDER

Requirements to notify or report to Health Canada

As a general reminder and in light of the potential impact the recent surge of COVID-19 cases in India may have on drug supply, we are reminding all market authorization holders (MAHs) and drug establishment licence (DEL) holders of certain obligations to notify or report to Health Canada (HC).

1. Requirements to Report **Drug Shortages and Discontinuations**

It is mandatory for a MAH to report, on drugshortagescanada.ca, drug shortages and discontinuations. Early reporting of anticipated and active shortages and discontinuations provides timely, comprehensive, and reliable information essential for drug manufacturers,

provincial and territorial governments, drug supply stakeholders, health care professionals and patients to prevent or manage the adverse health effects of drug shortages and discontinuations, helping to protect the health and safety of Canadians. However, this does not apply to consumer health products, personal care products, cosmetic-like drugs, toiletries or disinfectants as reflected in the letter received from Health Canada from the Assistant Deputy Minister Anne Lamar back in 2014.

Letter from Health Canada

2. Requirement to Report **Good Manufacturing Practices (GMP) compliance issues**

The Regulations also require Drug Establishment Licence (DEL) holders to report any event that may affect the quality, safety or efficacy of a drug fabricated, packaged/labelled, tested or stored by them or any of their suppliers.

Notifications should be sent to hc.el.applications-le.sc@canada.ca using the subject "C.01A.13 Notification". The notification should include a description of the event, and a description of the impact it may have on drug quality, safety, and/or efficacy. If available at the time of notification, include any actions that have been taken or are planned to address the product risks.

Please refer to Expedited Reviews of Drug Establishment Licences below if medically necessary and/or COVID-19 drugs are impacted and you wish to add a new supplier to your DEL.

Expedited Reviews of Drug Establishment Licence amendment applications

In cases where your foreign building(s) have been affected by events impacting the supply chain of medically necessary drugs and/or drugs deemed important to mitigate the risks of COVID-19, HC will consider expediting foreign building applications.

To help us prioritize requests, please include "COVID-19" or "MEDICALLY NECESSARY" in the subject line of any email correspondence related to these critical products and clearly indicate the following information in your cover letter:

- ✓ Drug brand name
- ✓ Drug identification number (DIN)
- ✓ Drug active ingredients
- ✓ DEL application number (if an application has previously been submitted for this foreign building)

Please note that a medically necessary drug is defined as a market-authorized drug in Canada which is used to prevent, treat or diagnose a serious or life-threatening disease or medical condition, for which there is no available alternative. Patient inconvenience alone is an insufficient reason to classify a drug as medically necessary. If there are other market-authorized drugs available, please provide detailed market data demonstrating that these products are not available. Please also complete and include the attached form (FRM-0378) with your submission.

Please submit requests to the Drug Establishment Licensing Unit at hc.el.applications-le.sc@canada.ca. Once received, we will assess your request and inform you whether the review will be expedited.

Environmental Updates

Various Publications Under the Chemicals Management Plan

Selenium and its compounds

The final order adding selenium and its compounds to the List of Toxic Substances to the CEPA was published. Selenium and its compounds are on the Cosmetic Ingredient Hotlist excluding Selenium sulfide as a prohibited ingredient. Please note that the final order is a generic listing on selenium and does not reflect certain Selenium compounds such as selenium sulfide. Since the listing is generic this might lead to some stigmatization for selenium sulfide containing products. Cosmetics Alliance has advocated and stressed that listing under Schedule 1 should not be generic as reflected in our comments on the Single Use plastics ban. We will continue our efforts to reduce any unnecessary stigma this may cause on products containing selenium sulfide.

Selenium and its compounds • *Canada Gazette* Notice	The final Order adding selenium and its compounds to the List of Toxic Substances to the *Canadian Environmental Protection Act, 1999* (CEPA) has been published.

Please do let us know if you have any questions or concerns

Plastic Manufactured Items

The final Order adding plastic manufactured items to Schedule 1 of CEPA has been published in the *Canada Gazette*, Part II yesterday. A table summarizing all comments received on the proposed Order, and Environment and Climate Change Canada and Health Canada's responses, is available on the Canada.ca (Chemical Substances) website. As you can see, the generic term plastic manufactured items was added to Schedule 1. Cosmetics Alliance did put an ask in our commentary for the single use plastic to discourage officials to be so generic on the Schedule 1 listing. Definition under the RIAS which provides the explanatory note on what is

constituted under Schedule 1 is anything that is made from plastic physically shaped into a design during manufacturing that has an express use and function from that design. This definition of manufactured plastics is verbatim from the New Substance Program. This effectively makes the conclusion that all plastic manufactured item will become plastic pollution and includes packaging as plastic waste. This may not be the focus of Risk Management efforts as the focus in on single use plastics (6 items part of the ban for single use plastics) but it does include in the listing any plastic including packaging. Our understanding is that over time this listing can be used to manage plastic packaging in the personal care product industry. It is an extensive listing and they didn't not take in account the limitation in the scope that we will included in our single use plastic commentary.

The response letters from the Minister of Environment and Climate Change to the notices of objection received on the proposed Order are available on the CEPA Registry.

Cosmetics Alliance is still in the process reviewing the CG2 notice in detail and follow-up with membership on possible next steps.

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

Talc

The proposed order adding Talc to Schedule 1 of the *Canadian Environmental Protection Act*, 1999 was published for a 60-day public comment period ending on July 21, 2021. For more information on Cosmetics Alliance response to the Talc Final Screening Assessment and our next steps please click here.

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