Cosmetics Alliance Updates

Smart Label Webinar - Implementation & Best Practices Technical Session

Wednesday, November-20-19 1:00 PM - 2:00 PM (Eastern Time)

Date: Wednesday, November 20, 2019
Time: 1:00 pm - 2:00 pm
Cost: Member: $50; Non Member: $150
This webinar is the second in a series designed to help companies understand more about SmartLabel. This technical session will demonstrate implementation strategies and review guides on the functionality of the platform.

Please be sure to have your technical staff attend this important webinar to learn more about the SmartLabel initiative.

Learn:
• How to get started
• How to build and maintain your SmartLabel landing pages
• How to inform your consumers about the information now available
SmartLabel is a managed cooperation of Associations across Canada and the United States.

REGISTER

Register for the Fall Regulatory Workshop! Hurry to get early bird

Date: December 12th 2019

Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business.

Important topics that will be covered:

• Sunscreen Pilot & Expansion
• NHPID Process
• Hotlist Updates / Process
• Updates to PLL, Compliance & Enforcement Approach
• Self Care Framework Updates from Summer & Fall
• Upcoming changes to Cost Recovery program for cosmetic-like drugs
• How Health Canada's Food and Drug Act Liaison Office can assist in facilitating conversations with officials

INTERACTIVE TRAINING SESSIONS

Cosmetics 101
Introduction to Cosmetics in Canada

December 3, 2019
2:00 - 3:30 plus 1/2 h quiz

Designed for New · Employees · New Cosmetics Alliance Members · Refresher Course

Objectives

- Learn the language of cosmetics in Canada
- Understand the set-up of Canadian Law
- Overview of the Cosmetic Regulations
- Enable attendees to access the Canadian market

Cosmetic Labelling 101 Introduction to Cosmetic Labelling for Canada

December 19, 2019
2:00 - 3:30 pm plus1/2 h quiz

Designed for New Employees and New Cosmetics Alliance Members

Objectives

- Lean the language of cosmetics in Canada
- Overview of the Cosmetic Labelling Regulations
- Learn how other Canadian regulations apply to cosmetics
- Understand how these regulations interact with each other

Health Updates:

DEL Bulletin #59 - Migration of Drug Establishment Licence (DEL) API Foreign Building Data to the DEL Database

Health Canada will be migrating the active pharmaceutical ingredients (API) foreign building information into the drug establishment licence (DEL) database called eCES. This will be followed by changes to the API application form (Table A) and associated processes. This change is expected to reduce the level of efforts required by applicants for submitting API foreign building applications. Health Canada is planning to start migration of this data in mid-November 2019. This notice applies to licence holders with a finished dosage form (FDF) or API building annex.

During the migration you will be provided with a new Table A form. After your data has been migrated, you will have to use the new version of Table A and you will no longer be required to submit a comprehensive Table A form with each application. Rather you will only be required to submit the changes you wish to make (add, remove, modify), simplifying the process.

Further guidance on the new application process will be made available in the instructions provided with the revised Table A form, prior to your migration.

Important note: At this time, you must continue to submit a comprehensive Table A using the current form. The change will only take effect after you receive a notice to say your data migration is complete.

During the migration you will receive three notices. The first notice will be sent about 2 weeks before your scheduled migration date and will provide a target date range for the start of your data migration. The second notice will be sent the day before your data migration begins. The last notice will be sent after the migration is complete and will provide you with an opportunity to review the migrated data.

You can continue to submit Table A applications after you have received the first notice. However, once you have received the second notice Health Canada asks that you refrain from submitting Table A applications until you are notified that your migration is complete. If you anticipate having to submit an important API application during your scheduled migration date, please inform Health Canada immediately after receiving the first notice so that arrangements can be made.

The amount of time required to migrate the data will vary from importer to importer.

Please note: There will be a blackout period for using the current Table A, however, if you need to use it during the black out period to maintain regulatory compliance, you can reach out to HC to inform them.

Linked below is a process flow for the implementation of this bulletin for your reference.

DEL Bulletin No. 59 – Process Flow

New Manager of Stakeholder Engagement at NNHPD

The Natural and Non-prescription Health Products Directorate (NNHPD) has announced that David Boivin has been hired as the new Manager of the Stakeholder Engagement Division. Most recently, Mr. Boivin was an Analyst for human resources project, planning and organization at Environment and Climate Change Canada (ECCC). Prior to that, he held other positions over a number of years at ECCC including in wildlife services, IT strategic planning and regulatory and policy analysis among others. He also co-owned a business organizing and creating social activities and theme events for a community of clients in Quebec. In addition to his new role at NNHPD, he working on his PhD in applied social sciences. The notice from Health Canada states, "David has a great interest in clear communication, use of new technologies in communicating, relationship building and working with stakeholders."

The Manager of Stakeholder Engagement plays an important role within the NNHPD including facilitating meetings and acting as a liaison between industry and Health Canada. Cosmetics Alliance looks forward to working with Mr. Boivin and his staff in his various capacities including NNHPD's bi-annual multilateral meetings.

Environmental Updates

Environmental Emergency Regulations, 2019

As you may be aware, Environment and Climate Change Canada's new Environmental Emergency Regulations, 2019 came into force on August 24, 2019, replacing the previous version of the Environmental Emergency (E2) Regulations (2011). This email is a reminder that as of August 24, 2019 all information required under the new E2 Regulations, 2019 must be submitted electronically in the new online Environmental Emergency Reporting System, accessible through the Single Window Information Manager (SWIM) available at: https://ec.ss.ec.gc.ca. This new electronic reporting system has permanently replaced the old E2 reporting system, which became inaccessible on the date mentioned above. Environment and Climate Change Canada would like to remind our current regulatees as well as regulatees previously included under the 2011 E2 regulations of their obligation, under the Transitional Provision in Section 22 of the E2 Regulations, 2019, to resubmit all required information into the Environmental Emergency Reporting System in SWIM if they fall under the new Regulations. This is required due to the significant changes to the Regulations as well as the implementation of a new online Environmental Emergency Reporting System. As such, you may be required to re-register facility(ies) previously registered in the old E2 reporting system database under the new Environmental Emergency Reporting System if any E2 substances on-site meet the threshold requirements under the new regulations. In most cases, thresholds have remained the same for substances that were subject to the previous version of the Regulations. Please refer to the new Environmental Emergency Regulations, 2019 to verify if your facilities are captured under the new regulations.

- Schedule 2 (Notice Regarding Substances Located at a Facility) must be submitted within 90 days of a facility becoming subject to the Regulations.
- For facilities that were registered under the previous regulation (2011) that met the threshold requirements for their E2 substances on the day the new E2 regulations came into force, Aug 24, 2019, the deadline for the Schedule 2 submission for those substances will be Nov 22, 2019.
- Schedule 3 (Notice Regarding the Preparation of an Environmental Emergency Plan) must be submitted within 6 months after the day on which an environmental emergency plan is required to be prepared under subsection 4(1).
- Schedule 4 (Notice Regarding the Bringing Into Effect of an Environmental Emergency Plan) must be submitted within 12 months after the day on which an environmental emergency plan is required to be prepared under subsection 4(1).
- Schedule 5 (Notice Regarding Simulation Exercises) must be submitted within 5 years after the day on which the environmental emergency (E2) plan is brought into effect.

With the implementation of the new E2 database, there are some steps that must be followed in order to successfully submit any of the required schedules. These steps are:

Step 1: Log-in to SWIM

To obtain additional guidance on SWIM in order to request and manage access to your organization in the Environmental Emergency Reporting System please refer to Instructional videos here.

Important Note: Once your profile in SWIM has been established, you will be asked to select your role for an Access Request to the Environmental Emergency Regulations Reporting System, please select "Regulatee and Contractor". The Public Safety Authority (PSA) role is meant for organizations such as Public Safety Canada; Royal Canadian Mounted Police (RCMP); Police departments; Fire departments; Federal/Provincial Health & Paramedic Organizations; Provincial Emergency Response Officials; Municipal Emergency Management Officials; etc.

Step 2: Accessing the Environmental Emergency Regulations Reporting System as a E2 Regulations Regulatee and Contractor

For guidance on how to report using the Environmental Emergency Reporting System please refer to the Online Reporting System Guidance for the Environmental Emergency Regulations, 2019. Additional information can also be found on our program website at https://www.canada.ca/en/environment-climate-change/services/environmental-emergencies-program/regulations.html

Important Note: Once you have reached the final page of a Schedule submission on the Environmental Emergency Regulations Reporting System you must save your work then return to the bottom of the final submission page to and press submit to finalize the submission.

Please be advised that we are in the final stages of publishing the Technical Guidelines for the Environmental Emergency Regulations, 2019, which is expected to be published in the fall of 2019.

Any questions related to SWIM login and registration should be directed to ECCC's Information Manager at SS_Admin@ec.gc.ca. For any questions regarding the SWIM GCKey please refer to the GC Key Frequently Asked Questions page.

Any questions related to the Environmental Emergency Regulations Reporting System can be directed to ec.ue_gigue2_swim.ec@canada.ca and any questions related to the Regulations should be directed to the regional compliance promotion officer of your region listed at https://www.canada.ca/en/environment-climate-change/services/environmental-emergencies-program/regional-contacts.html.