Regulatory Essentials – March 7, 2018

Cosmetics Alliance Update

Register for Cosmetics Alliance Spring Regulatory Workshop

Cosmetics Alliance 2018 Spring Regulatory Workshop is a must for members seeking the latest updates and information on everything regulatory.

Date: Thursday, April 12, 2018
Registration: 8:15 - 9:00 am
Workshop: 9:00 am - 4:30 pm
Location: Hotel Omni Mont-Royal, Montreal, Quebec

Topics Include:

- Consumer Products Safety Program Updates
- Natural and Non-prescription Health Products Updates
- Self-Care Products Framework
- Regulatory Operations & Regions Branch and DEL Updates
- Environment and Climate Change Canada Updates

View Preliminary Agenda

Member Engagement Session:

Cosmetics Alliance will be hosting a Member Engagement Session at the end of the Workshop, so be sure to attend the whole day. This Session will provide an opportunity for members to share their concerns and issues with Cosmetics Alliance staff and fellow attendees. Workshop delegates are encouraged to plan their travel arrangements accordingly to ensure active participation for this one-of-a-kind setting.

Register for Workshop

Health Updates

New Manager in Bureau of Product Review and Assessment

Recently the Non-prescription Drug Evaluation Division acquired a new manager in BPRA. Dr. Shiva Ghimire will be replacing Dr. Ratna Bose.

Dr. Shiva Ghimire is a veterinarian by training and holds a Ph.D. in Veterinary Science from the University of Sydney, Australia. Prior to joining NNHPD, he had been working with the Veterinary Drugs Directorate (VDD) of Health Canada as a Team Leader (since 2009) and a reviewer (2004 – 2009) coordinating human safety assessments of veterinary drugs used in food producing animals. Cosmetics Alliance would like to take this opportunity to welcome Dr. Shiva Ghimire.

Drug Submission Performance Quarterly Reports

The Therapeutics Product Directorate (TPD), Biologics and Genetic Therapies Directorate (BGTD) and Natural and Non-prescription Health Products Directorate Drug Submission Quarterly Reports are now available.

The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of pre-market drug review process against performance service standards. The quarterly report compares five consecutive quarters from October – December 2016 to October – December 2017. The reports are broken down by operational areas. The TPD report summarises performance metrics for pharmaceuticals. The BGTD report summarises performance metrics for biologics. The NNHPD report summarises performance metrics for non-prescription (over-the-counter) and disinfectant drugs. Within each report, statistics are provided by submission type and show the number received, the number in workload, the number of decisions and the number of approvals.

Quarterly Drug Submission Performance Report – EN

BGTD

TPD

NNHPD

Quarterly Drug Submission Performance Report – FR

BGTD

TPD

NNHPD

https://www.cosmeticsalliance.ca/drug-submission-performance-quarterly-reports/

DEL Bulletin LEPPP No. 22 – Notice of Publication of GMP Documents

On February 28, 2018, the Health Products Compliance Directorate posted four Drug Good Manufacturing Practices (GMP) documents. Cosmetics Alliance provided comments on the GUI -0001 and GUI-0023.

· Good manufacturing practices guide for drug products (GUI-0001),

· Risk classification guide for drug good manufacturing practices observations (GUI-0023)

· Good manufacturing practices for medical gases (GUI-0031)

· Annex 1 to the Good manufacturing practices guide – Manufacture of sterile drugs (GUI-0119)

The New Government of Canada Regulatory Cooperation Website

The Regulatory Cooperation Directorate launched their new website. The site features up-to-date information about regulatory cooperation initiatives and consultations, as well as detailed guidance on reporting regulatory barriers to trade.

Sunscreen Pilot Updates

Cosmetics Alliance has been informed that Regulatory Operations and Regions Branch is reaching out to participants of the Sunscreen Pilot as part of their 360-degree analysis. Please contact your CA Regulatory Team at regulatory@cosmeticsalliance.ca if you have been contacted by Health Canada in this regard.

Key Updates:

- RORB has started their 360-degree analysis of the pilot
- We have reminded RORB that this analysis should be brief, as the measurement of success should be linked back to the purpose of reducing redundancy and duplicative testing, and not a measurement of GMP considerations and traceability
- Ask has been made for product expansion to include: Dandruff, Athlete's Foot, Medicated Skin Care, Antiseptic Skin Cleansers, Acne, Diaper Rash, Throat Lozenge and Oral Care (Triclosan/Fluoride and CPC) products
- Ask has been made for expansion to other jurisdictions to include any foreign site listed on a Drug Establishment Licence
- We have asked they deliver further details on the Sunscreen Pilot at the CA Spring Regulatory Workshop on April 12th, which RORB will be attending

Notice Administrative Processing of Submissions and Applications: Human Drugs and Disinfectants

Health Canada announced the publication of the Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs. The document replaces the Changes in Manufacturer's Name and/or Product Name Policy (CMPN), written in 1998 and updated in 2001, 2015 and 2017.

Highlights

- 3-month delay before implementation to allow industry sufficient time to become familiarized with the new guidance document
- Contact lens disinfectants have been removed from the guidance document effective Feb 2018.
- Implementation for disinfectant drugs is April 1, 2019
- Grandfathering introduced for previous deviations

Please review the guidance document and let your CA Regulatory Team know if you have any questions.

Natural Health Product License Amendment and Notification Form Release

Health Canada's Natural and Non-prescription Health Products Directorate (NNHPD) has released their PLAN (Product Licence Amendment and Notification Form) and associated draft guidance document to associations involved in the development of the PLAN.

Product license holders can use this form in order to update their company contact or product information. Cosmetics Alliance member volunteers provided feedback to the NNHPD during a beta-testing activity in December 2017 which helped form this version of the PLAN.

Cosmetics Alliance strongly encourages its members to use the PLAN for their amendments and notifications over the next few months, and to provide feedback to the NNHPD at NHP_Initiative_PSN@hc-sc.gc.ca.

Application to Standards Council of Canada Canadian Mirror Committee to ISO/TC217

Standards Council of Canada is reaching out to Cosmetics Alliance members to participate in the Canadian Mirror Committee to ISO/TC217 Cosmetics and network with global experts. Response is required by Tuesday, March 20, 2018. Please click here for information regarding the committee.

Post-Consumer Waste Updates

Ontario General Fee Setting Policy – Register for March 9 Final Webinar Consultation

In order to give stakeholders additional time to review the draft General Fee Setting Policy, Fee Setting Methodology and Tire Fees documents, the Ontario Resource Productivity and Recovery Authority (RPRA) has moved its third and final round of consultations on its General Fee Setting Policy to Thursday **March 9, 2018 from 10:00 to 12:00**. If you have not yet registered, you can do so here. Visit the RPRA's website to view the Round Three Consultations documents. The deadline to send comments to consultations@rpra.ca is now **March 19, 2018**.

Work Continues on the Proposal to Amend Ontario's Blue Box Program Plan

On February 15, 2019 Stewardship Ontario and the Ontario Resource Productivity and Recovery Authority (RPRA) announced that the proposal to amend the Blue Box Program Plan remains a work-in-progress and continues to be assessed against the stakeholder feedback Stewardship Ontario received during Phase 1 and 2 of the consultation process. As such, Stewardship Ontario elected not to submit a program plan to the Resource Productivity & Recovery Authority on February 15, 2018, and we await next steps.

Wind Up of Waste Electrical and Electronic Equipment Program Announced

On February 8, 2018 the Ontario Minister of the Environment and Climate Change issued directions under the *Waste Diversion Transition Act, 2016* to Ontario Electronic Stewardship to wind up the Waste Electrical and Electronic Equipment Program by June 30, 2020. This will enable the transition of electronic waste to individual producer responsibility under the *Resource Recovery and Circular Economy Act, 2016*. The Ministers' letters and additional information are posted to RPRA's WEEE Program Wind Up Consultation webpage.