Regulatory Essentials – September 25, 2019

Cosmetics Alliance Updates

SmartLabel - Providing Consumers with Easy Access to More Information Than Could Ever Fit on a Label: A Free Webinar

Join us on September 25th to learn more about how SmartLabel is changing what the future of labelling looks like in Canada and how it is allowing consumers to make more fully informed decisions.

This free webinar is designed to help companies understand:

- How SmartLabelling will increase e-commerce sales and how it can reduce inefficiencies and improve user experiences for e-retailers, logistics providers and consumers
- How SmartLabel™ Canada is designed to support the Canadian Drug Facts Table (eCDFT)
- Opportunities it can provide to Reduce Packaging sizes and how the technology is more environmentally sustainable
- Ways it offers consumers hundreds of product attributes, such as nutrition information and ingredients as well as facts that go well beyond the label

SmartLabel is a managed cooperation of Associations across Canada and the United States.

Many companies are already engaged and if your company isn't, this webinar is for you!

Date: September 25, 2019

Time: 1 – 2 p.m.

Presenter: Jim Flannery

To Register please RSVP to mdavis@cosmeticsalliance.ca.

Natural Health Products Management of Applications Policy Training Session

Date: Wednesday, October 9, 2019
Time: 2:00 pm - 3:30 pm
Cost: Member: $150; Non-Member: $250

Attendees Limited to 25

Objectives

- Learn the key important considerations
- Understand the changes you need to plan for
- Recognize how Health Canada develops policy
- Understand the new types of application classifications
- Learn how applications are processed and their outcomes

*Training will include exercises, a quiz and a training certificate for your training file.

Course Length: 1 hour
Plus Quiz Time: 1/2 hour

Register

Health Updates

EPA Chief Directs Agency to Dramatically Reduce Animal Testing

The Environmental Protection Agency announced September 10, 2019 a plan to dramatically reduce its reliance on animal testing to assess the dangers of chemicals, pledging to end nearly all experiments on mammals by 2035. A directive from EPA Administrator Andrew Wheeler says the agency will scale back requests for and funding of mammal studies by 30 percent by 2025; after 2035, any use of such tests will require the approval of the agency's administrator. The memo also commits $4.25 million in grants to five universities for developing alternative experiments that "will minimize and hopefully eliminate the need for animal testing," Wheeler told reporters. Full story here.

Mandatory Use of the Electronic Common Technical Document (eCTD) Format

The eCTD format for regulatory activities allows Health Canada to move towards a common submission intake process, standardize and improve its business processes and tools, and align its regulatory requirements with those of other international regulatory authorities. Health Canada has been accepting regulatory activities in eCTD format since 2004. As of December 2018, 93 percent of regulatory activities under Part C, Division 8 of the Food and Drug Regulations for human drugs have been provided in this format.

The purpose of this updated notice is to communicate Health Canada's intention to expand the scope of regulatory activity types where filing in eCTD format is a mandatory requirement. This notice is updated to incorporate external stakeholder feedback that was submitted during the consultation period. As Health Canada continues to move towards a harmonized intake process, additional regulatory activity types (e.g. all Division 1 regulatory activities) will be mandatory in eCTD format. Health Canada will inform stakeholders in advance of making such requirements. Regulatory activity types for the following product lines currently remain out of scope for filing in eCTD format; they must be filed in "non-eCTD electronic-only" format:

- Medical Devices
- Veterinary Drugs

Regulatory transactions in eCTD format should be prepared as prescribed in the Guidance Document – Preparation of Regulatory Activities in eCTD Format, and must be sent via the Common Electronic Submissions Gateway (CESG), when applicable. Refer to the CESG information page for details.

For the personal care products industry, it is important to note the product applications that are not mandatory below.

Recommended in eCTD Format (not mandatory) - List of Regulatory Activity Types:

Division 1 (Prescription and non-Prescription Human Drugs)

- Application for Drug Identification Number (DINA)
- Application for Drug Identification Number - Biologic (DINB)
- Application for Drug Identification Number - Disinfectant (DIND)
- Application for Drug Identification Number - Category IV Product (DINF)
- Post-Authorization Division 1 Change (PDC)
- Post-Authorization Division 1 Change - Biologic (PDC-B)
- Post-DIN Notification (for DINA only)
- Yearly Biologic Product Report (YBPR) - Biologic
- Pre-Submission Meeting Information (MPDIN)
- Periodic Safety Update Report (PSUR) or Periodic Benefit Risk Evaluation Report (PBRER) when provided to the Marketed Health Products Directorate (MHPD)
- Risk Management Plan (RMP), when provided to MHPD
- Other Post-market Vigilance data (Undefined Data Post-Market Vigilance (UDPV)) requested by MHPD
    - Post-Authorization commitments - Post market Vigilance (PA-PV)
    - Post-Authorization Act and Regulations - Post market Vigilance (REG-PV)
    - Issue Related Summary Report (IRSR-PV)
    - Risk Communication – Post market Vigilance (RC-PV)
    - Patient Safety/Advertising Ad-Hoc Post market requests (PSA-PV)

Division 8 (for Human Drugs only)

- Undefined Regulatory Activity (UDRA)
    - Notification of Discontinued Sale (DIN cancellation)
    - Notification of interruption of sale

Master Files

- Conversion of existing
    - Type I Master Files - Drug Substance
    - Type II Master Files - Container Closure Systems and Components
    - Type III Master Files - Excipients
    - Type IV Master Files - Drug Product

<u>Update on Compliance Monitoring Projects from HPCD</u>

The Health Product Compliance Directorate (HPCD) will soon begin to carry out its planned proactive risk management projects for 2019-20. The HPCD is responsible for the delivery of a national compliance and enforcement program to manage potential risks posed to Canadians by health products under its scope.

These proactive projects are conducted to proactively verify, promote and/or gather information on industry compliance with Canadian regulatory requirements. These projects complement our other compliance and enforcement activities such as our routine drug inspection program and complaint-based compliance verifications.

This year, HPCD will conduct compliance monitoring projects, also called “planned reviews”, on the following topics:

1) **Good manufacturing practices for natural health products ("NHP GMPs"):** Follow-up visits with licence holders visited during previous projects to verify implemented corrective actions
2) **Performance natural health products (NHPs):** Testing of licensed NHPs indicated as workout supplements to screen for undeclared ingredients or contamination
3) **Advance Notice of Importation:** Site visits to verify the labelling of products imported via the Advanced Notice of Importation Process Pilot (A.01.044 of the *Food and Drug Regulations*)
4) **Drug establishment licences (DEL) foreign sites & terms and conditions:** Site visits to verify compliance with Health Canada's notices to DEL holders to stop importation from non-compliant foreign sites & with terms and conditions
5) **Veterinary health products (VHP) and medically important antimicrobials (MIA) for food-producing animals and animals intended to be consumed as food:** Site visits to verify specific regulatory requirements of VHPs and MIAs

In support of Health Canada's Regulatory Transparency and Openness Framework and the Treasury Board Secretariat's commitment to Open Government, the findings of these projects could be posted on Health Canada's website. Information on previous projects is available at the following link.

Further information about Health Canada's planned reviews is available at the following link.

Post-Consumer Waste Updates

CSSA Annual Steward Meeting – Register Now!

The Canadian Stewardship Services Alliance (CSSA) 2019 Annual Steward Meeting (ASM) will take place on **Thursday, October 24** at **2:30 - 4:00 p.m. EDT.** Register here. Based on steward feedback, this year's event will again be webcast only. The ASM, held on behalf of CSSA partner stewardship programs in Ontario, BC, Saskatchewan and Manitoba, provides stewards with updates on packaging and paper recycling program performance along with next year's program budgets and material fee rates. Contact jjames@cssalliance.ca if you have any questions about the ASM.