Regulatory Essentials – January 6, 2021

Cosmetics Alliance Update

Membership Renewal 2021

With 2021 fast approaching, we **need your involvement and commitment** with the renewal of your company's membership in order to help Cosmetics Alliance Canada advance the collective interests of the cosmetics and personal care products industry.

Steps to Renew

Pilot Certification Program with the Shark Water Foundation

Long time CA members Brian and Sandy Stewart of Tribute Entertainment continue the work of their late son, internationally acclaimed film-maker Rob Stewart of the Sharkwater Foundation who worked to raise awareness of the need to protect endangered shark species by ending the use of shark-derived squalene in cosmetics. CA will be working with the Sharkwater Foundation in the new year to scope a pilot certification program to ensure cosmetic manufacturers are sourcing plant-based squalene from suppliers. CA members interested in participating can contact mdavis@cosmeticsalliance.ca.

CA Guidance to Help Determine "Essential Health and/or Hygiene Products" Related to Shutdowns due to Pandemic

We have recently been contacted by several members on an urgent basis concerning the issue of determining which cosmetics and other personal care products are to be considered "essential health and/or hygiene" products. As we have been advised, this determination has been left to the discretion of retailers in some jurisdictions including Quebec or is being considered by various public health authorities including in Manitoba.

The attached CA Information Document (English French) has been prepared to provide some suggested guidance on how this can be approached based upon the definitions and regulation of our products included in Canada's *Food & Drugs Act*. Please feel free to share this document with any public health authorities or retailers should you require a reference.

Additionally, feel free to direct any public health official or retailer to Susan Nieuwhof (snieuwhof@cosmeticsalliance.ca, 647-980-5161) at Cosmetics Alliance to help address any issues or questions.

Health Update

Health Canada's Annual Adjustment of Fees for Drugs and Medical Devices

Each year Health Canada's fees for drugs and medical devices are subject to an annual adjustment. The Department is committed to providing stakeholders with advanced notice to adjust their business plans accordingly.

As of April 1, 2021, the human and veterinary drug and medical device fees subject to the *Fees in Respect of Drugs and Medical Devices Order* for fiscal year 2021 – 2022 will be adjusted by a negative Consumer Price Index of 0.2%. Fees for other regulatory and non-regulatory activities and services will be subject to the established annual fee increase of 2%. The fees will be adjusted as follows:

Fee Line	Authority for Adjustment	Annual Adjustment
Human and Veterinary Drug and Medical Device Pre-Market Evaluation, Right to Sell and Establishment Licence	*Fees in Respect of Drugs and Medical Devices Order*	CPI -0.2%
Veterinary Drug Dealer's Licences	*Service Fees Act* (fees set as per *Fees for Licensed Dealers for Controlled Drugs and Narcotics (Veterinary Use) Fees Regulations* under *Financial Administration Act)*	CPI -0.2%
Drug Master File	Ministerial Authority	2%
Certificate of Pharmaceutical Product	Ministerial Authority	2%
Certificate of Supplementary Protection	*Certificate of Supplementary Protection Regulations*	2%
Human Drug Dealer's Licences	*Fees in Respect of Dealer Licences Regulations*	2%

Notices of these fee adjustments were published in *Canada Gazette*, Part I on December 5, 2020. To view these the adjusted fees please visit the following link: http://www.gazette.gc.ca/rp-pr/p1/2020/2020-12-05/html/index-eng.html.

Related fee webpages and application forms will be updated to reflect the adjusted fees and will be published on Health Canada's website prior to April 1, 2021.

CORRECTION – Requesting Feedback on Clinical Trials Records Retention Proposal

The email from ROEB on December 21, 2020 included attachments on cost-benefit analysis survey in English and French. Those documents incorrectly requested that responses be returned by October 30, 2020.

To confirm, Health Canada is requesting that completed surveys be returned by January 25, 2021. Please find below updated cost-benefit analysis surveys, which reflect this correction.

Cost Benefit Analysis Survey – EN/FR

Update on Filing Submissions Electronically

The page below lists all the guidance documents and other related documents to provide companies with information on how to file their submissions electronically in eCTD and non-eCTD formats. This page also includes information on current consultations and pilots, and additional information related to the Regulatory Enrolment Process and the Common Electronic Submission Gateway, the addition of Veterinary medicine to the list excluded from the New Dossier ID Process, removal of the date beside the Dossier ID Request Form for Pharmaceutical/Biologic Dossiers.

View article…

Nitrosamine update to market authorisation holders of human pharmaceutical, biological, and radiopharmaceutical products

Please find below an updated Q&A document to assist affected market authorization holders in responding to Health Canada's October 2, 2019 letter regarding nitrosamine impurities. This document also provides guidance to market authorization holders of biological and radiopharmaceutical products in their response to the attached December 15, 2020 letter on nitrosamine impurities.

HIGHLIGHTS:

- Expansion of product scope to Schedule D drugs (Biologics) and Schedule C drugs (Radiopharmaceutical). Timelines as follows:
    - Step 1 – Completion of risk assessments by November 30, 2021;

    - Step 2 – Confirmatory testing by November 30, 2023;
    - Step 3 – Changes to the market authorization by November 30, 2023.
- Reminder, for all other DINs (as communicated on August 10th, 2020):
    - Step 1 – Completion of risk assessments by March 31, 2021;
    - Step 2 – Confirmatory testing by October 1, 2022;
    - Step 3 – Changes to the market authorization by October 1, 2022.
- What you can do if you can not meet the Step 1 deadline (Question 7).
- The MAH letter dated December 15, 2020 highlights a number of potential sources of nitrosamine impurities which have been identified via root causes analyses and provides further guidance when conducting risk assessments
- The Q&A Document has been updated to include:
    - New information:
        - How changes to the market authorization should be submitted (Q12)
        - What the limits of quantitation that should be validated for analytical procedures for nitrosamine detection (Q28)
        - When routine testing for nitrosamines should be included in API and/or drug product specifications (Q29)
        - What potential control options there are for nitrosamine impurities in the API (Q. 30)
        - Details on the number of batches which should be tested as part of confirmatory testing (Q. 32)
        - What to do if multiple nitrosamines are detected (Q. 23)
        - Updates to acceptable intakes for nitrosamine impurities (Q. 21)
    - Updated information has been added to the following questions: 1, 4, 7, 11, 14, 15, 17-20, 22, 24 and 26

HC Q&A Document on Nitrosamines EN/FR

MAH Letter English EN/FR

Post-Consumer Waste Update

RPRA Approves Transition Plan with Conditions that Impact Steward Fees

The Resource Productivity and Recovery Authority (RPRA) has approved Stewardship Ontario's Blue Box Program Transition Plan, subject to certain conditions, including the deferral of the Material Cost Differentiation (MCD) Methodology. Use of the Four-Step Fee Methodology was approved.

In the Transition Plan, Stewardship Ontario proposed to use MCD as a new input to fee-setting to provide better and more reliable data on the cost impacts of each material in the recycling system. Other Blue Box programs in Canada have already started the process of replacing the Activity Based Costing (ABC) Methodology with MCD and have set 2021 steward fees using the Four-Step Fee Methodology and a 50/50 blend of the MCD and ABC methodologies.

Stewardship Ontario took the same approach in its proposed Transition Plan. They presented the 2021 steward fee schedule at the Annual Steward Meeting (ASM) while highlighting that it was still subject to approval as part of RPRA's review and consultation on the Transition Plan.

With RPRA's condition to defer MCD, they had to recalculate 2021 fees using the Four-Step Fee Methodology and ABC Methodology alone, without MCD. Please review the new, approved 2021 steward fee schedule here.

Stewardship Ontario will be reviewing RPRA's reasons for the deferral of MCD and will be responding with a plan that aims to implement MCD in 2022.

Other conditions for RPRA's approval of the Transition Plan relate to the following:

- The impact of adopting MCD on the in-kind amount paid to participating communities.
- Perceived competitive impacts of adopting MCD prior to transition.
- Scope of Stewardship Ontario's Code of Conduct.
- Access to Stewardship Ontario's data.
- Maintaining program performance.
- Updating the plan through the course of transition.
- Provision of information to RPRA.

Background information on the development of the Transition Plan is available on the Stewardship Ontario website.

If you have any questions, please contact consultation@stewardshipontario.ca.