Regulatory Essentials - November 14, 2018

Cosmetics Alliance Update

Introduction to Natural Health Products

Date: Tuesday, December 11, 2018

Time: 1:00 p.m. – 2:30 p.m.

Cost: Member - $225 Non-Member - $395

Objectives:

- Overview of the Natural Health Product Regulations
- Understand what a Natural Health Product is
- Understand the basic requirements for:
    - Product Licensing
    - Site Licensing
    - GMPs
    - Labelling
    - Clinical Trials
    - Reaction Reporting
- Enable attendees to access the Canadian Market

Register

Health Updates

Consultation on the Pause-the-Clock for Drug and Medical Device Establishment License Applications

Health Canada is consulting on Pause-the-Clock for Drug and Medical Device Establishment License. The Pause-the-clock mechanism will apply to all Establishment applications for drugs and medical devices. This includes application that are subject to user fees, as well as those that are not. The pause-the-clock does not apply to:

- Applications that include a foreign on-site inspection by Health Canada
- Processes that are not related to an application (e.g. regular domestic inspections)

Some important highlights that would trigger Pause-the-clock:

- Deficiency notice issued
- Delayed inspection
- Meeting request
- Opportunity to be heard (OTBH)
- Late payment of fees

Benefits of Pause-the-clock:

- Pausing the clock can avoid the application receiving decision or HC processing an application that does not represent what the applicant wants or needs

- A pause-the-clock will not delay HC reviews.
- Will enable HC to report on performance in a more precise manner
- Will give HC the opportunity improve performance standard from the data collected.

The pause-the-clock proposal contains proposed model, proposed triggers and benefits of the proposal. Please take the time to review the proposal. If you have any comments or concerns please reach out to your CA Regulatory Team at regulatoy@cosmeticsalliance.ca. Stakeholders can directly submit their comments to RORB for DEL to hc.del.questions-leppp.sc@canada.ca and for Medical Devices to hc.mdel.questions.leim.sc@canada.ca.

Consultation on Proposed Revisions to the Guidance Document: Management of Drug Submissions

Health Canada is revising the Management of Drug Submissions Guidance (MDSG). There has not been a major revision to the MDSG since 1993. The guidance is being updated to reflect current processes and procedures and to provide additional information and references relevant to the filing of submission or application. The information in the guidance is also being reorganised to mirror the process that submission and applications, or post-market pharmacovigilance documents.

In addition to the general updates noted above, Health Canada is proposing the following changes to the guidance, which require consultation:

1. Remove the sections relating to Update Notices (section 5.5.1 A) and Advance Notice Letters (section 6.4) as the Notice and Letter are no longer used given the objective of the Department to review within the performance target standards.
2. Remove the paragraphs regarding information which must be submitted within 180 days of the original submission under subsection (b) of Section 5.5.2 Unsolicited Information. This requirement is no longer needed as the submission of unsolicited final reports of ongoing safety studies within 180 days of the original submission rarely occurs, since a complete data package should be included in the submission at the time of filing. If completed studies show any negative safety findings or risk information, sponsors can submit this information at any time.
3. Amend the existing 15-day standard timeline for responses to clarification requests (section 5.5.1B) to account for the type of submission or level of clarification being requested. The change will bring greater predictability for sponsors as it allows for the response time to better reflect the type of submission/application under review.

Please review the guidance document and provide your comments to Cosmetic Alliance as we will be sending in comments to regulatory@cosmeticsalliance.ca. We also encourage you to send in your comments directly to Bureau of Policy, Science and International Program email account: hc.policy.bureau.enquiries.sc@canada.ca.

Technical Issue with the Drug & Health Product Inspection Database

The Drug & Health Product Inspection Database (DHPID) is a useful tool in order to have access to information on inspection and establishment licenses. Recently, DHPID has been made aware of technical issue preventing some inspection information from being updated on their website. DHPID is working on fixing the issue. Also, note that some types of inspection found in DHPID may not accurately reflect the inspection definitions provided in POL-0011. A

small number of foreign inspections that would typically be classified as Re-Assessments will appear as Regular Inspections until the database issue has been solved and Cosmetics Alliance will notify you once the issue has been resolved. Should you have any questions about the information please email hc.del.questions-leppp.sc@canada.ca.

Mutual Recognition Agreement of Active Pharmaceutical Ingredient in Australia-Canada

In Australia, manufacturers of APIs are regulated under the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations 1990. API manufacturers in Australia are required to hold a GMP license that authorizes the manufacture of APIs. As of November 1, 2018, Health Canada and TGA concluded an agreement to include APIs under the scope of the Mutual Recognition Agreement on Conformity Assessment in Relation to Medicines Good Manufacturing Practice Inspection and Certification Between the Government of Canada and the Government of Australia. Therefore, Health Canada accepts GMP Certificates of Compliance, issued by the TGA, for APIs fabricated/manufactured in Australia as evidence of compliance to GMP.

Benefits to the MRA

Stakeholders from Canada will benefit form the exchange of GMP Certificates between TGA and Canada, therefore reducing regulatory burden to obtain information from their foreign buildings.

The GMP requirements described in the regulations of respective countries must be met. Health Canada's GMP Requirements according to C.02.009 Raw Materials testing, require the Finished Dosage Form (FDF) manufacturer to fully test starting material upon receipt or perform confirmatory testing when there is a certification programme in place as long as requirements of C.02.010 are met. This will continue to be applicable to APIs regardless of the origin of import. As such there will be re-control exemptions upon import.

Publication of the Revised Bundle 4 Monographs to Address "Statements to the Effect OF"

On November 13, 2018, the Natural and Non-prescription Health Products Directorate released the Bundle 4 of Monographs to address Statements To The Effect. The bundle 4 can be found on the Natural Health Products Ingredients Database on the What's New Page. Below is the list of the monographs released.

1. 5-HTP
2. Bilberry - Buccal
3. Bilberry - Oral
4. Black Pepper
5. Black Walnut
6. Blessed Thistle - Oral
7. Blessed Thistle - Topical
8. Burdock - Oral
9. Burdock - Topical
10. Caffeine
11. California Poppy
12. Cascara Sagrada
13. Cayenne - Oral
14. Cayenne - Topical
15. Chamomile, German - Buccal

16. Chamomile, German - Oral
17. Chamomile, German - Topical
18. Chamomile, Roman
19. Chaste tree
20. Dandelion
21. Dandelion Juice
22. Deglycyrrhizinated licorice - Buccal
23. Deglycyrrhizinated licorice - Oral
24. Fennel, Bitter
25. Fennel, Sweet
26. Ginger
27. Ground Ivy - Oral
28. Ground Ivy - Topical
29. Kutki
30. Psyllium - Plantago afra
31. Psyllium - Plantago arenaria
32. Psyllium - Plantago ovata
33. Sage - Buccal
34. Sage – Oral

Environmental Updates

Revised – In commerce List - Formal End of Acceptance of Substance Nominations

The Notice to Announce the Formal End of Acceptance of Substance nomination to the Revised In-Commerce List (R-ICL) was published on November 3, 2018. This final notice indicates that the end of acceptance of substance nominations to the R-ICL will occur on November 3, 2019, providing stakeholders with one year to conclude the nomination of any outstanding eligible substances to the R-ICL and follows a 60-day comment period. From November 3, 2019 onward, manufacturers and importers who wish to market a new substance for use in FDA-regulated products in Canada that is not already listed on the R-ICL must submit a notification under the NSNR (Chemicals and Polymers) and NSNR (Organisms).

If you would like to make a nomination please provide the substance nomination information to Health Canada, by completing and submitting the appropriate nomination form and providing proof of in commerce in *Food and Drugs Act* products marketed in Canada between January 1, 1987, and September 13, 2001. There are two forms:

1. one form is intended for the nomination of chemicals and polymers
2. the second form is intended for the nomination of living organisms.

To obtain the copy of the form please email RICL-LRSC@hs-sc.gc.ca.

The Draft Screening Assessment for Anthraquinones Group and Solvent Violet-13

On November 3, 2018, a notice with respect to the draft screening assessment for 7 substances in the Anthraquinones Group and the risk management scope for Solvent Violet 13 were published in the Canada Gazette, Part I. It is proposed that Solvent Violet 13 is carcinogenic and causes developmental effects through dermal and oral exposure (harm to human health).

The draft screening assessment is open for a consultation for 60 days. The 7 substances in the Anthraquinones group is not entering in levels that is harmful to human health or the environment. Please note that Solvent Violet 13 and Violet 2 have the same CAS RN of 81-48-1. Below are the Information Sheet on Anthraquinones, Synopsis of the Draft Assessment of Anthraquinones and the Risk Management Scope of Solvent Violet 13.

Information Sheet on Anthraquinones – EN

Information Sheet on Anthraquinones – FR

Synopsis of the Draft Screening Assessment on Anthraquinones – EN

Synopsis of the Draft Screening Assessment on Anthraquinones – FR

Risk Management Scope of Solvent Violet 13

Draft Screening Assessment of Poly(amines) Released

The draft screening assessment of Poly(amines) consists of nine substances which were evaluated under the second phase of polymer rapid screening but were classified as requiring further assessment to evaluate ecological concerns. Out of the nine substance of significance to the personal care products industry is Polyquaternium-7 for CASRN 26590-05-6. It is proposed that the substances do not meet any of the criteria set out in CEPA.

New Risk Assessment Summaries Available on the New Substances Program

The New Substances Notification Regulations (Chemicals and Polymers) require new substance to undergo an assessment of their potential adverse effects on the environment and human health to determine whether they have potential to pose a risk before the Canadian Market. To increase the transparency of the program the Standing Committee on the CEPA and Health Canada are publishing summaries of risk assessment reports. The published summaries include the most complete notification for chemicals and polymers, animate products of biotechnology as well as notifications where control measures are applied. The initiative provides the public an opportunity to learn more about the risk assessments of new substances that are being manufactured and/or imported in Canada.