Regulatory Essentials – January 9, 2019

Cosmetics Alliance Update

With 2019 fast approaching, we **need your involvement and commitment** with the **renewal of your company's membership** in order to help us advance the collective interests of our industry. Click here for the steps to renew.

Health Updates

NNHPD Released 2018 Fall-Winter Updates

On December 28, 2018, NNHPD released its 2018 Fall-Winter Updates. Please take the time to review the update as there are key information on Self-Care Framework, Web-based NHP PLA Form, Plain Language Labelling, Cannabis and Monographs.

NNHPD Newsletter – EN

NNHPD Newsletter – FR

Annual License Review DEL Calculator and Certifies Statement of Revenue

The Drug Establishment Licencing Unit and the Cost Recovery Invoicing Unit (CRIU) provided the Certified Statement of Revenue (CSR) template and the Drug Establishment Calculation Chart. These tools have been created to assist DEL holders in calculating the total fee for their DEL.

CSR -ERC Template – Human or Veterinary

CSR-ERC Template – Veterinary Only

DEL Calculation Chart

DEL Annual Licence Review Webinar

The DEL office is hosting a free webinar on the DEL Annual License Review. Below are the dates for the webinar. The webinar will present a basic tutorial on the Annual Licence Review application form including how to complete the DIN Application Annex. This webinar is ideal for new establishments or applicants submitting their Annual Licence Review application for the first time.

- **January 14th, 2019 from 10:00 AM to 11:30 PM EDT (English)**

  https://gts-ee.webex.com/gts-ee/j.php?MTID=m19f5c720a3a5fff03a53232ebc8b24b1

- **January 14th, 2019 from 1:30PM to 3:00PM EDT (French)**

  https://gts-ee.webex.com/gts-ee/j.php?MTID=me20ce3a42579669b24de599604120956

- **January 17th, 2019 from 10:00AM to 11:30PM PM EDT (English)**

  https://gts-ee.webex.com/gts-ee/j.php?MTID=m60ed4dbc31d62bfcb3734614383c31f0

To Join one of the two English sessions – January 14th, 2019 from 10:00 AM to 11:30 PM EDT or January 17th, 2019 from 10:00AM to 11:30PM PM EDT (no advance registration required):

1. At the time of the webinar, click on the webinar link provided above.

2. If a password is required, enter the meeting password: ALR2019

3. Follow the instructions on the screen.

If you have any questions, comments and/or concerns pertaining to the ALR webinar, please contact us: HC.DEL.ALR-EAL.LEPP.SC@canada.ca.

Guidelines for Environmental Control of Drugs During Storage and Transportation (GUI-0069)

Health Canada is pleased to announce the release of a draft guidance document for a 90-day stakeholder consultation from December 20, 2018 to March 20, 2019:

- Guidelines for environmental control of drugs during storage and transportation (GUI-0069)

This revised guidance document contains new information. Plain language principles to make the document easier to read and understand have been considered in rewriting and formatting the document. It will continue to support compliance with Good Manufacturing Practices requirements prescribed in Part C, Division 2 of the *Food and Drug Regulations* (FDR).

The key changes to the document are listed below.

How to participate

1. Review guidance documents

The consultation documents is below.

2. Submit comments

Please email your comments to hc.hpil.consultation-ipsop.sc@canada.ca using the comment form. The 90-day consultation period is from December 20, 2018 to March 20, 2019 inclusively.

Comments can also be mailed to:

Health Product Inspection and Licensing Division
Health Product Compliance Directorate
13th Floor, Jeanne Mance Building
200 Eglantine Driveway, Tunney's Pasture
Address Locator # 1913D
Ottawa Ontario K1A 0K9

Overview of Key Changes

GUI-0069: Guidelines for environmental control of drugs during storage and transportation is applicable to all persons (individuals and companies) involved in the storage and transportation of drugs for human use, drugs for veterinary use, clinical trial drugs for human use, Active Pharmaceutical Ingredients (APIs) and samples distributed to professionals. Changes include:

- Updates to warehousing and storage including training requirements for personnel and Mean Kinetic Temperature (MKT) information added;
- Updates to transportation section including expanded contingency plans, written documentation and procedure requirements and expanded temperature mapping requirements and exemptions;
- Updates to containers and labelling section with provisions for labelling of small shipping containers and appropriate language to be used;
- Updates to the documentation section with expanded requirements and details for written agreements including contracted third parties.

GUI-0069 – EN

GUI-0069 – FR

Annex F Consultation Form- EN

Annex F Consultation Form- FR

Changes to the lists of Release of GMP for API (GUI-0104)

Health Canada released the consultation for GUI-0104: *Good manufacturing practices for active pharmaceutical ingredients* for a 90-day period, from December 31, 2018 to March 31, 2019.

This revised guidance document contains new information. Plain language principles to make the document easier to read and understand have been considered in rewriting and formatting the document. It will continue to support compliance with Good Manufacturing Practices (GMP) and Drug Establishment Licence requirements prescribed in Part C, Division 1A and Division 2 of the Food and Drug Regulations (FDR). The key changes to the document are listed below.

How to participate

1. Review guidance documents

The consultation document is below.

2. Submit comments

Please submit comments using the attached comment form. You may email your comments to hc.api.question-ipa.sc@canada.ca or mail them to the address, below. The consultation period runs from December 31, 2018 to March 31, 2019.

Health Product Inspection and Licensing Division
Health Product Compliance Directorate
13th Floor, Jeanne Mance Building

200 Eglantine Driveway, Tunney's Pasture
Address Locator # 1913D
Ottawa Ontario K1A 0K9

Overview of Key Changes

- An expanded scope to include veterinary active pharmaceutical ingredients (API) and importation for the purpose of compounding
- Added information to clarify that the scope includes cannabis APIs
- Updated information to align with applicable sections of the current Good Manufacturing Practices guide for drug products (GUI-0001)
- Added clarity to help you satisfy GMP regulatory requirements depending on the API activities being conducted at the building
- New information to provide clarity regarding analytical test methods
- New information regarding re-packaging, testing and sampling requirements
- New information regarding re-testing of APIs
- Updated information on stability testing and API intermediates
- Added definitions related to antimicrobial resistance and antimicrobial agents
- Added definitions related to cannabis APIs

Health Canada recognizes there are ongoing discussions regarding the potential implementation of a new Self-Care Framework. However, until regulatory amendments are finalized to support the Self-Care Framework, Health Canada will continue to update guidance documents according to existing requirements under the Food and Drugs Act and Regulations. Upon implementation of the Self-Care Framework, Health Canada will revise guidance documents as appropriate.

GUI-0104 Comment Form - EN

GUI-0104 Comment Form – FR

GUI-0104 – EN

GUI-0104 - FR

Changes to the Drug Submission Under Review

Health Canada is committed to being transparent and open about its activities and to making timely and useful information available about health products and health product submissions. To support this commitment, Health Canada is sharing more information about drugs it is reviewing, including company names and generic drug submissions. For comments or questions please contact hc.opprs.enquiries-enquettes.bprse.sc@canada.ca

Drug and Medical Device Databases Document Released

Health Canada is pleased to announce the release of the document Drug and Medical Device Databases.

This document provides a comprehensive list of Health Canada's drug and medical device databases and includes an overview of the information available in each database.
The guidelines are designed to facilitate access to these databases and to inform stakeholders on what information is available.
Questions or concerns regarding this guidance document can be directed to:
Website Publications Unit
Office of Submissions and Intellectual Property
Email: hc.tp.web.publications.sc@canada.ca

Consultation of Regulation of Edible Cannabis, extracts and Topicals

Health Canada is launching a 60-day public consultation on draft regulations addressing additional cannabis products, namely edible cannabis, cannabis extracts and cannabis topicals.

The draft regulations are designed to better protect the health and safety of Canadians through strict regulatory controls and to enable the legal industry to displace the illegal market. These cannabis products will be permitted for legal sale under the Cannabis Act no later than October 17, 2019.

Key Point for Topicals:

- No health or cosmetic claims
- Must contain cosmetic grade ingredients

Please take the time to review the draft regulation and let your CA regulatory team know if you have any comments or concerns. We will be consolidating all comments and sending it to Health Canada.

Multi-Regional Clinical Trials Draft Training Program

Health Canada is pleased to provide you with the draft training program for your review. The program is only available in English currently. Registration is expected to open by early January.

When: February 26-28, 2019

Where: John G. Diefenbaker Building (Old City Hall) – 111 Sussex Drive, Ottawa, Ontario

What: Didactic and Case-based learning, presentations, and open discussion
Who: Regulators from Health Canada (reviewers and inspectors), and individuals from industry, academia, and non-profit organizations
Registration: No cost. Registration details will be circulated by early January.
Learning Objectives:

- Describe the standards of Good Clinical Practice (GCP) and key considerations in Multi-Regional Clinical Trials (MRCTs) design as set out in ICH E6(R2) and ICH E17 guidance, respectively
- Use case studies to apply the changes of ICH E6(R2) addendum and ICH E17 to increase the acceptability of MRCT data by multiple regulatory authorities
- Demonstrate practical approaches to fulfilling the requirements of ICH E6(R2) and ICH E17

For Regulators:

- Describe and demonstrate best practices to assess clinical trial regulatory submissions, including study design, data packages, essential documents, reports, and filings for alignment with ICH GCP and MRCT
- Describe inspection methodologies to assess clinical trial conduct for alignment with ICH GCP and MRCT standards, including review of corrective actions.

For Stakeholders:

- Gain better understanding and knowledge of Health Canada expectations with regards to compliance with the Canadian clinical trial regulations and GCP inspection processes

For any questions please contact hc.ich.sc@canada.ca .

Draft Canada Training Program

Notifying Health Canada of Foreign Actions – Guidance Document for Industry

The draft guidance *Notifying Health Canada of Foreign Actions - Guidance Document for Industry*, https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/foreign-actions-profile/guidance-document.html, and the new regulation C.01.050, http://www.gazette.gc.ca/rp-pr/p2/2018/2018-05-02/html/sor-dors84-eng.html, that came into force November 20, 2018. HC is preparing an on-line reporting form to assist with compliance. The guidance and the form consider comments received from stakeholders during the consultation process.

Release of ICH:Q3C(R7): Impurities: Guideline for Residual Solvents

Health Canada released the implementation of International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) Guidance Q3C(R7): Impurities: Guideline for Residual Solvents

This guidance has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. The ICH Assembly has endorsed the final draft and recommended its implementation by membership of ICH.

In implementing this ICH guidance, Health Canada endorses the principles and practices described therein. This document should be read in conjunction with this accompanying notice and with the relevant sections of other applicable Health Canada guidances. This and other Guidance documents are available on the ICH Website. Please note that the ICH website is only available in English. If you would like to request a copy of the French version of the document, please contact the HPFB ICH inbox.

It is recognized that the scope and subject matter of current Health Canada guidances may not be entirely consistent with those of the ICH guidances that are being introduced as part of our commitment to international harmonization and the ICH Process. In such circumstances, Health Canada-implemented ICH guidances take precedence.

Health Canada is committed to eliminating such discrepancies through the implementation of a phased-in work plan that will examine the impact associated with the implementation of ICH guidances. This will result in the amendment or, depending on the extent of revisions required, withdrawal of some Health Canada guidances.

Should you have any questions or comments regarding the content of the guidance, please contact:

Health Canada - ICH Coordinator
E-mail: hc.ICH.sc@canada.ca

NNHPD Client Services Update

The Natural and Non-prescription Health Products Directorate (NNHPD) held a teleconference call December 11th, 2018 with industry associations to discuss current challenges in responding to client service inquiries.

The NNHPD is currently facing an ever-increasing volume of client requests regarding the licensing of natural health products and non-prescription drugs. This increase in demand, tied with finite resources and a reactive approach to client support, leaves no room for process improvement. These pressures have also challenged the NNHPD's ability to meet its 10-business day service standard for responding to client service inquiries. To improve client support without compromising service delivery, NNHPD has been investigating potential streamlining opportunities for client support function.

There are two main channels by which the NNHPD currently receives client requests: telephone calls on its client service line [613-960-8827], and emails through its generic account [hc.nnhpd-dpsnso.sc@canada.ca]. A live-to-live person communication approach for every contact is unrealistic and unsustainable, especially when faced with high volumes of calls.

NNHPD will implement two changes as of December 21st, 2018. These changes, outlined below, will bring about process improvements, enable the NNHPD to direct its finite resources towards reducing the current backlog of email inquiries, and provide a predictable and reliable service to clients going forward.

· Implementation of an auto-responder: The NNHPD will no longer answer calls placed to the client service line [613-960-8827], but will gradually transition into a full electronic model. The phone line will remain active while in transition to the generic email communication system for client requests. Full transition to email is expected by March 2019, at which point the phone line will be discontinued. During that transition period, for any calls received, a pre-recorded audio message (i.e., auto-responder) will be delivered, which will advise callers of the change and redirect them to the generic email account. Informed by data collected to date on the most FAQs, options will also be explored to include in the auto-responder the most FAQs and answers.

· Use of the email auto-reply function: A frequently asked question received through our email channel pertains to the status of an application. The auto-reply function will be populated with information regarding routine email requests and FAQs, including those pertaining to an application that has been received and is being processed by the NNHPD within the applicable performance standard. The NNHPD will continue to review each email received and verify, for

each status request, that the application has been received. However, for those, a response will only be provided when an issue is identified with the application (e.g., application not received).

Environmental Updates

Prohibition of Asbestos and Products Containing Asbestos

The *Prohibition of Asbestos and Products Containing Asbestos Regulations* (the Regulations) and the related amendments to the *Export of Substances on the Export Control List Regulations* (ESECLR) were published in *Canada Gazette*, Part II, on October 17, 2018.

Please be advised that the Regulations and ESECLR amendments will come into force on **December 30, 2018**.

Factsheet: Asbestos and Products Containing Asbestos Regulations – EN

Factsheet: Asbestos and Products Containing Asbestos Regulations – FR

Final Screening Assessment for Eugenol and Isoeugenol Derivatives Group

The Minister of the Environment and the Minister of Health have conducted a screening assessment of two of four substances referred to collectively under the Chemicals Management Plan as the Eugenol and Isoeugenol Derivatives Group. Phenol, 2-methoxy-4-(2-propenyl)- (commonly referred to as eugenol) was identified as a priority for assessment, as it met categorization criteria under subsection 73(1) of CEPA. Rose, *Rosa canina*, ext. (commonly referred to as *Rosa canina* extract) was considered a priority on the basis of other ecological concerns. It is concluded that eugenol and *Rosa canina* extract do not meet any of the criteria set out in section 64 of CEPA.

Substances in the assessment:

CAS RN	*Domestic Substances List* name	Common name(s)
97-53-0	Phenol, 2-methoxy-4-(2-propenyl)-	Eugenol
84696-47-9 [a], [b]	Rose, *Rosa canina*, ext.	*Rosa canina* extract

Final Screening Assessment for the Rapid Screening of Substances with Limited General Population Exposure

An important initiative under the Chemicals Management Plan (CMP) is the rapid screening of substances that the Government considers to be of low concern. The rapid screening approach makes use of both qualitative and quantitative steps to efficiently evaluate the likelihood that a substance may cause harm, given conservative estimates of exposure. At each step in the rapid screening process, any substance that appears to present a potential for harm will be identified as requiring further assessment. For those substances that pass through all steps of the rapid screening without being identified as requiring further assessment, the Government will conclude that the substances are unlikely to meet the criteria set out in Canadian Environmental Protection Act, 1999 (CEPA 1999). 171 substances for which potential for direct exposures to humans was not anticipated were identified and were therefore considered to be candidates for

a rapid screening approach. Please take the time to review the substances that were part of the rapid screening. Please reach out to your CA regulatory team if you have any questions or

Final Screening Assessment for Calcium 2-ethylhexanoate and 2-ethylhexyl-2-ethylhexanoate

The Minister of the Environment and the Minister of Health have conducted a screening assessment of calcium 2-ethylhexanoate and 2-ethylhexyl 2-ethylhexanoate. These substances were identified as priorities for assessment, as they met the categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns. Their Chemical Abstracts Service Registry Numbers (CAS RNs), their *Domestic Substances List* (DSL) names and their common names are listed in the table below. It is concluded that calcium 2-ethylhexanoate does not meet any of the criteria set out in section 64 of CEPA and that 2-ethylhexyl 2-ethylhexanoate meets one or more of the criteria set out in section 64 of CEPA. 2-Ethylhexyl 2-ethylhexanoate meets the bioaccumulation criteria but not the persistence criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

Two-year Rolling Work Plans Published – CMP

The Two-Year Publication Plan tab visually indicates time periods during which assessment products will be published for the third and fourth years of the third phase of the CMP (April 2018 to March 2020). This includes both Science Approach Documents and Screening Assessment Reports involving the substances listed under the Substances List tab. Also shown are Screening Assessment Reports initiated in earlier phases of CMP; however, substances addressed in these documents are not included in the list in the Substances List tab.
The substances list and two-year rolling publication plan will be updated annually. Additional information on the types of approaches indicated in the Substances List is available in the Risk Assessment Toolbox.

Changes at Healthy Environments and Consumer Safety Branch

Christine Norman, Director of Existing Substances Risk Management Bureau retired on December 14, 2018. Deborah Ratzlaff will be acting from December 17, 2018 to December 21, 2018 and from January 7, 2019 to March 31, 2019.

- Julie Chouinard will be acting for me from December 24, to December 30, 2018.

- Virginie Bergeron will be acting for me from January 2 to January 4, 2019.

- Deborah Ratzlaff can be reached at Deborah.ratzlaff@canada.ca or 613-954-6310.

- Julie Chouinard can be reached at Julie.chouinard@canaca.ca or 613-952-5365.

- Virginie Bergeron can be reached at virginie.bergeron@canada.ca or 613-954-8348.

Government of Canada Signs Environmental Cooperation Agreement with the United States and Mexico

The Minister of Environment signed the new Agreement on Environmental Cooperation among the Governments of Canada, the United States of America, and the United Mexican States. This environmental cooperation agreement complements the ambitious environment chapter of the recently signed Agreement between Canada, the United States of America, and the United Mexican States and strengthens environmental cooperation between the three trade partners. The environmental cooperation agreement addresses international environmental challenges and identifies ways to seize opportunities presented by the new Agreement between Canada, the United States of America, and the United Mexican States.

Canada, Mexico, and the United States have agreed to collaborate on a broad range of environmental issues, including reducing pollution; supporting strong, resilient, low-carbon economies; conserving and protecting nature, biodiversity, and habitats; and supporting clean growth, sustainable development, and sustainable use of natural resources.

Robust environmental provisions ensure Canadian companies compete on a fair footing with companies in other jurisdictions, help drive clean innovation throughout industry, support good jobs, and protect the clean air and clean water.

Post-Consumer Waste Updates

Ontario Minister Issues New MHSW Direction to Stewardship Ontario

The Minister of the Environment, Conservation and Parks has amended the timelines associated with the wind up of the Municipal Hazardous or Special Waste (MHSW) Program. The Minister has directed Stewardship Ontario (SO) to wind up the program for single-use batteries on June 30, 2020. This change will allow for a coordinated policy approach with the wind up of the Waste Electrical and Electronic Equipment Program on June 30, 2020. All other deadlines outlined in SO's wind-up letter from April 2018 remain in place. SO must submit a wind-up plan to the Authority no later than June 30, 2019 and the remaining designated wastes under the MHSW Program will wind up on December 31, 2020. Contact the Ministry via Zarnaaz.miran@ontario.ca by **January 4, 2019** if you are interested in consultations webinars taking place January 9 and January 14, 2019.