Regulatory Essentials – January 22, 2019

Cosmetics Alliance Update

Membership Renewal

We need your involvement and commitment with the 2020 renewal of your company's membership in order to help Cosmetics Alliance advance the collective interests of the cosmetics and personal care products industry.

Renew Your Membership

Health Updates

Updates to the Cosmetic Ingredient Hotlist

Health Canada released the advance Notice to Stakeholders of proposed updates to the Cosmetic Ingredient Hotlist on Monday, January 13, 2020. For those of you who attended our Fall Regulatory Workshop in December, you are already aware of the ingredients listed in the notice as the Consumer & Hazardous Products Directorate provided CA members with a pre-notice of the proposed hotlist updates. The advance notice reflects the information and discussions heard at the Fall Regulatory Workshop.

We will be engaging with this proposal and will be working on consolidating input on the advanced notice through our PCMA and RAIS committee. In respect to the PHA entry and Retinoids proposal we will be forming individual Science Task Forces to address these ingredients with the PCMA and RAIS committee. We will be sending a call out to the respective committees in the upcoming weeks.

If you did not attend our Fall Regulatory Workshop, please take the time to review the proposal and let us know if you have any questions or concerns.

Two New Guidance Available on Health Canada's Consumer Product Safety Program

Two new guidelines are available on Health Canada's Consumer Product Safety Program's web page:

1. Guidelines for importing, exporting or transhipping consumer products and cosmetics into Canada for commercial purposes

   EN – Policy
   FR - Policy

2. Guidelines to the Consumer Product Safety Program Policy on Compliance Verification Projects

NNHPD Client Service Teleconference Call Canceled

Considering the Multilateral Meeting on February 4, 2020, Health Canada will be postponing the Client Services Teleconference Call Update, scheduled for January 22, 2020. Please note an update on performance will be given at the Multilat. Health Canada will confirm a new date for the Teleconference Call, in early spring with an email invitation, once the date is determined.

Cosmetics Alliance will be attending the Mutli-Lateral Meeting and will provide an update on Client Services on the February 19th Regulatory Essentials.

DEL Bulletin No. 66 Introduction of Telecommunication Tools During GMP Inspections

This notice is to inform you that Health Canada intends to introduce the use of certain telecommunication tools during GMP inspections in an effort to assess the feasibility of a virtual or offsite inspection model and to align with other modernization and environmental initiatives.

Beginning in January 2020, Health Canada's GMP inspectors will introduce the use of web-conferencing during certain, pre-selected drug establishment inspections where the regulated activity is any combination of importation, wholesale, and/or distribution. These activities are being considered initially to determine whether GMP requirements can be adequately assessed through documentation review, either in full or in part. Inspections where other regulated activities are in scope may be considered at a later date, based on feedback from these inspections. Feedback from our inspectors and stakeholders will be collected following the virtual inspections to determine the effectiveness of using web conferencing.

Whether a GMP inspection is performed onsite or offsite via telecommunication, an overall inspection rating will be assigned in accordance with applicable Health Canada guidelines and policies

What you can expect during a virtual or offsite GMP inspection

Pre-Inspection

If your establishment is selected for a virtual (or offsite) inspection, the inspection team will notify you as part of the pre-inspection process and will provide detailed instructions on connecting to the web-conference, including how to use the necessary tools within the application. You will also have the opportunity to inform the inspector in the event your establishment is unable to participate in a web-conference.

During the Inspection

In most cases, the inspection team will start the inspection virtually, using the web-based conferencing application to host the opening meeting, review the inspection schedule, and begin the review of documents and records. You may also experience breaks in the meetings throughout the virtual portion of the inspection to allow for offline document review. The inspector will use his/her discretion to determine whether the inspection will also require an on-site inspection portion.

After the Inspection

The closing meeting may be conducted virtually. The inspector(s) will determine whether to hold the meeting on-site or via web-conference.

You may be asked to answer a few questions regarding the virtual inspection process once it has been completed. The feedback Health Canada receives from stakeholders will help inform any future process changes.

Annex A – Frequently Asked Questions

1. What web-conferencing application will be used during a virtual GMP inspection?

The CISCO Webex application will be used to conduct portions or all of a GMP inspection virtually.

2. Do I need a Webex account to participate in a virtual inspection?

No, only the host of a Webex meeting is required to have an account. The inspector(s) assigned to the inspection will host the meetings and provide a link to the session. Participants will be asked to input their name and email to join.

3. What types of information and records will be reviewed during a virtual inspection?

The following records are examples of documents that will likely be reviewed during a virtual inspection:

- Personnel CVs/training records
- Organizational charts
- Standard operating procedures, work instructions, etc.
- Quality system documents, including records/management of investigations, complaints, deviations, etc.
- Qualification/validation documents
- Computerized systems, databases

All documents, however, which fall under the scope of a GMP inspection may be subject to this method of review.

4. Will the web-conference make use of video?

Yes, both the inspector and the regulated party are expected to enable video during the virtual inspection whenever possible.

5. Will the web-conference include a virtual tour of the facility?

Inspectors will determine whether to proceed with a virtual or on-site tour of the facility.

6. Who is expected to participate in the web-conference?

Whether a GMP inspection is conducted onsite or via telecommunication, the regulated party is responsible for identifying the individuals who are required to participate.

7. How long is a web-conference expected to last?

The duration of the offsite portion of the inspection will vary. The inspector will use his/her discretion to determine the extent of a virtual inspection and will schedule the inspection with you accordingly.

DEL Bulletin No. 67 Nitrosamines Stakeholder Information Webinar

Health Canada is holding a Stakeholder Information Webinar on the topic of nitrosamine contamination of human pharmaceutical products on January 31, 2020. This webinar is a follow-up to the previous Health Canada communications on this topic, notably the letter to all Marketing Authorization Holders (2 October 2019) and associated Questions and Answers document (4 December 2019).

The purpose of this session is to provide an opportunity for discussion of this issue with Health Canada and other Stakeholders. Health Canada will provide contextual overviews of the situation relating to nitrosamine impurities in pharmaceuticals and review the Questions and Answers document shared with Stakeholders on 4 December 2019. Stakeholders will have an opportunity to share their experiences, successes and challenges in addressing the issue of nitrosamine contamination.

Please note the webinar is full and there is a waitlist. To get on the waitlist please register here.

Environmental Updates

FDA Meeting on Testing Methods for Asbestos in Talc

On January 10, 2020, the US FDA published the Public Notice of an upcoming meeting (February 4, 2020) that they will be hosting regarding "Testing Methods for Asbestos in Talc". This Notice also incorporates a call for comment/input pertaining to the method proposals that they will be discussing in this upcoming meeting – the corresponding deadline for comment is March 4, 2020.

CA Canada will not be participating in this meeting; however, we encourage members that are interested in this ingredient to follow-up accordingly to hear first-hand where these discussions go. Instructions are included as to how to submit a request to make a presentation at this meeting, if members are interested.

In the interim, if you have any thoughts or input concerning any of these proposed methods – please drop us a note at regulatory@cosmeticsalliance.ca, as there is likely to be significant international interest in these developments moving forward. In particular, we are interested in any feedback regarding any technical challenges that may be attributed to these proposals and any commentary regarding the reliability, predictability and/or repeatability of the methods.

We are aware that the supplier community (through representations via the Industrial Minerals Association of North America IMA-NA)) are actively engaged with this Notice and will be following up accordingly.

Various Publications Under the Chemicals Management Plan

Poly(alkoxylates/ethers) Group Draft Screening Assessment

The draft screening assessment for the Poly(alkoxylates/ethers) Group was published for a 60-day public comment period ending on February 5, 2020. The anticipated publication of the final screening assessment is December 2020. The risk to Canadian from substances in the Poly(alkoxylates/ethers) is considered to be low and unlikely to cause ecological harm.

Sodium Cyclamate and Cyclohexylamine

The draft screening assessment for sodium cyclamate and cyclohexylamine was published for a 60-day public comment period ending on February 5, 2020. The anticipated publication of the final screening assessment is December 2020. While exposure of the population to these substances is not of concern at current levels, these substances are associated with human health effects of concern. Therefore, there may be a concern for the human health if exposure were to increase.

Cosmetics Alliance will not be submitting comments to both draft screening assessment unless interest is shown by membership. If you have questions or concerns please reach out to the regulatory team at regulatory@cosmeticsalliance.ca

Other Update

PCPC GMP Workshop – April 23, 2020

The 5th PCPC GMP Workshop is coming to Dallas on April 23, 2020. For more information and to register please email Stephanie Johnson (johnsons@personalcarecouncil.org)