Regulatory Essentials – August 22, 2018

Cosmetics Alliance Updates

Register for Cosmetics Alliance Fall Regulatory Workshop

While Summer might almost be over, Fall is definitely something to look forwards too as Cosmetics Alliance will be hosting their annual Fall Regulatory Workshop. This year's Fall Regulatory Workshop will be on:

Date: Wednesday, October 10, 2018
Registration: 8:15 a.m. - 9:00 a.m.
Workshop: 9:00 a.m. - 4:30 p.m.
Location: The Omni King Edward Hotel, Toronto

Cosmetics Alliance Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". You won't want to miss this opportunity to hear from government officials, industry experts and Cosmetics Alliance staff first hand on issues that will directly affect your business.

Register before Monday, September 10 to take advantage of our early bird pricing. Receive discounted pricing when you send more than one representative from your company.

To Register: https://www.regonline.ca/registration/Checkin.aspx?EventID=2527886

Health Updates

Stakeholders Engagement Webinars for Good Manufacturing Practices

In June, the Drug Establishment Licensing Office held a stakeholder engagement webinar pertaining to the Good Manufacturing practices guide for drug products (GUI -0001), the Risk classification guide for drug good manufacturing practices observations (GUI-0023) and the Annex 1 to the Good Manufacturing practices guide – Manufacture of sterile products (GUI-019) in addition to updates on the Drug GMP inspection Program. Please see below for the webinar recording and the GUI-0001 presentation deck. For questions related to the Drug Establishment Licensing Requirements, please contact the Drug Establishment Licensing Unit at: hc.del.questions-leppp.sc@canada.ca. For importers with questions related to submissions in support of demonstrating GMP compliance of foreign buildings where licensable activities are conducted with respect to drugs, please contact: hc.foreign.site-etranger.sc@canada.ca.

English Webinar Recording

GUI-0001 Presentation Deck – EN

GUI-0001 Presentation Deck – FR

Cost-Benefit Analysis Survey for Environmental Risk Assessment of Medicinal Ingredients in Drugs

Last week, Cosmetics Alliance Members may have received a Cost-Benefit Analysis Survey (below) pertaining to *"Environmental Risk Assessment of Medicinal Ingredients in Drugs"*. This Health Canada survey is being conducted in advance of a new regulatory proposal seeking to amend the Food and Drug Regulations to reflect new regulatory requirements for environmental

risk assessment of medicinal ingredient(s) in human and veterinary drugs. This proposal is the culmination of years of consultations following the promulgation of the Canadian Environmental Protection Act, 1999 (CEPA 1999) which came into force, September 2001.

Having been engaged with these consultations since their inception, members will recall that there were two consultation streams that were being pursued with regards to the development of appropriate environmental assessment approaches for substances in Food and Drug regulated commodities, specifically a 'Class 1' approach for active medicinal ingredients in prescription drug products; and a 'Class 2' approach for all other substances in F&D products (including foods, cosmetics, natural health products, medical devices, and non-prescription products). In fact, Cosmetics Alliance's Beta Montemayor served as the Co-Chair for the multi-stakeholder advisory group that was tasked with providing input on a proposed regulatory approach for 'Class 2' Environmental Assessment Regulations (EARs) between 2008 and 2012.

Health Canada notified Cosmetics Alliance earlier this year of their intent to proceed with a proposal to address 'Class 1' EARs, and as such, this development was well anticipated. However, what wasn't anticipated was the extension of this proposal to "cosmetics with Drug Identification Numbers (DINs)", as appears to now be reflected in the survey as recently published by Health Canada. Cosmetics Alliance is in the process of urgently seeking clarification on the proposed scope – which goes far beyond the intent of the previous consultations and which would yet again impose a different set of regulatory consequences for low-risk drug products that would not extend to similar products that are classified as Natural Health Products (NHPs). On this basis, we have also outreached to officials at NNHPD to ensure that they are aware of these developments and potential implications from a Self-Care Framework (SCF) perspective.

Bottom line… the 'Class 1' approach was intended only to apply to active medicinal ingredient(s) in prescription drug products, biologics and radiopharmaceuticals. On this basis, engagement with this survey should not be necessary. However, the scope as presently worded, does implicate ALL drug products (including cosmetics, with DINs). Cosmetics Alliance is actively and urgently seeking clarity in the proposed scope and will be engaging accordingly. This will inform how best to engage with this survey moving forward. In the interim, we strongly recommend that members 'hold off' on any engagement with this survey until further clarity can be confirmed regarding the intended scope.

Reducing the Environmental Impact of Drugs – Update to Stakeholders

Association Survey – EN

Association Survey – FR

Business Survey – EN

Business Survey – FR

Overview Document – EN

Overview Document - FR

Drug Submission Performance Quarterly Reports (April -June 2018) TPD, BGTD & NNHPD

The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of pre-market drug review process against performance service standards. The quarterly report compares five consecutive quarters from April – June 2017 to April – June 2018. The reports are broken down by operational areas. The Therapeutic Product Directorate (TPD) report summarises performance metrics for pharmaceuticals. The Biologics and Genetic Therapies Directorate (BGTD) report summarises performance metrics for biologics. The Natural and Non-prescription Health Products Directorate (NNHPD) report summarises performance metrics for non-prescription (over-the-counter) and disinfectant drugs. Within each report, statistics are provided by submission type and show the number received, the number in workload, the number of decisions and the number of approvals. Please find below the reports for each directorate.

BGTD

NNHPD

TPD

Environmental Updates

CCME Draft Framework for Zero Plastic Waste Online Survey

The Canadian Council of Ministers of the Environment (CCME) recently shared their zero plastic waste online survey. The CCME is working to improve Canada's record on preventing, reducing and recycling plastic waste. CCME's Waste Reduction and Recovery Committee, co-chaired by representative of Yukon Environment, Québec's Ministry of Sustainable Development, Environment and the Fight Against Climate Change, and Environment and Climate Change Canada, is leading the zero plastic waste work. Below is the CCME's Zero Plastic Waste Framework. The framework is balanced and focuses on the big picture of reducing plastic waste. One positive highlight is microbeads is not mentioned in the framework. To provide feedback on the framework CCME has created a short online survey which closes on Friday, August 31, 2018. Cosmetics Alliance will be taking part in the survey and engaging with feedback supporting the framework. If you have any questions regarding the framework and survey or if you have any comments on the framework, please let us know.

CCME Draft Framework for Zero Plastic Waste – EN

CCME Draft Framework for Zero Plastic Waste – FR

Draft Screening Assessment of Fatty Acids and Derivatives Group

On August 18, 2018, the Government of Canada released the draft screening assessment of 10 substances in the fatty acids and derivatives group to address the potential harm to Canadians and to the environment. Below are the fatty acids and derivative groups that were assessed. Canadians may be exposed to these substances through the use of cosmetics, natural health products and non-prescription health products based upon a comparison of levels to which Canadians may be exposed to and the levels associated with health effects, along with the consideration of international assessments, the risk to human health from these substances is considered to be low. As a result of this assessment, the Government is proposing that undecylenic acid, ALA, tung oil, fats and glyceridic oils, margosa, tall oil acid, potassium tallate,

evening primrose oil, trimer acid, dimer acid, and ethylhexyl cocoate are not harmful to human health at current levels of exposure. The Government is also proposing that these substances are not entering the environment at levels that are harmful to the environment.

Substance Group	CAS RN	Common name	DSL name	Draft screening assessment	Proposed conclusion on section 64 criteria	Follow-up activities
Fatty Acids and Derivatives Group	112-38-9	Undecylenic acid	10-Undecenoic acid	HTML	Does not meet	None planned at this time
	463-40-1	α-Linolenic acid (ALA)	9,12,15-Octadecatrienoic acid, (Z,Z,Z)			
	8001-20-5	Tung Oil	Tung Oil			
	8002-65-1	Fats and Glyceridic oils, margosa	Fats and glyceridic oils, margosa			
	61790-12-3	Tall oil fatty acid (tall oil acid)	Fatty acids, tall-oil			
	61790-44-1	Potassium tallate	Fatty acids, tall-oil, potassium salts			

Substance Group	CAS RN	Common name	DSL name	Draft screening assessment	Proposed conclusion on section 64 criteria	Follow-up activities
	90028-66-3	Evening Primrose Oil (EPO)	Evening primrose, Oenothera biennis, ext.			
	68937-90-6	Trimer acid	Fatty acids, C18-unsaturated, dimers			
	61788-89-4	Dimer acid	Fatty acids, C18-unsaturated, trimers			
	92044-87-6	Ethylhexyl cocoate	Fatty acids, coco, 2-ethylhexyl esters			