Regulatory area to be addressed	***Over-the-Counter Products*** Health Canada and U.S. Food and Drug Administration will coordinate and adjust their respective Over-the-Counter (OTC) monographs development processes for OTC drugs to reduce the regulatory burden on stakeholders.

Work stream A	**Cooperation on Sunscreens**

Department/Agency	 United States	 Canada
	U.S. Food and Drug Administration	Health Canada

Planned initiatives and sub-deliverables		Date
On November 26, 2014, President Obama signed the Sunscreen Innovation Act (SIA) which amends the U.S. Federal Food, Drug, and Cosmetic Act to establish a process for the review and approval of over-the-counter (OTC) sunscreen active ingredients. In 2015, FDA published a draft guidance on sunscreens which describes the safety and efficacy requirements that each sunscreen ingredient will need to meet in order to be included in the OTC sunscreen monograph. Following FDA's review of the draft guidance comments, including those received from Health Canada, FDA will publish the final guidance in late 2016. FDA will also continue to share its work under SIA with Health Canada through annual meetings. Under Canada's Consumer Health Products (CHP) Framework, Health Canada continues to make improvements to the regulation of sunscreens. As Health Canada updates its approach to sunscreens, the Department will continue to share its work with FDA (e.g. recent and upcoming work on the review of sunscreen ingredients).		
	• FDA will issue a Final Guidance on Sunscreens	Late 2016
	• FDA and Health Canada will coordinate and discuss relevant sunscreen policies in Canada and the U.S.	Summer 2017

Work stream B	Engagement on policy development as part of the Consumer Health Products Framework

Department/Agency	United States	Canada
		Health Canada

Planned initiatives and sub-deliverables	**Date**
Building on work that began under the Consumer Health Products Framework in 2014, Health Canada is modernizing its approach to self-care products, including natural health products, non-prescription ("over-the-counter") drugs and cosmetics. Health Canada aims to regulate products with similar risk profiles in a similar fashion so that requirements for bringing them to market will be more consistent and easier to understand. It may appear that products grouped together on retail store shelves are regulated in the same way, but that is not the case. They may all fall under one law in Canada, the *Food and Drugs Act*, but they are however, regulated under three separate sets of regulations under this law. These products are considered low risk but not all of them are supported by the same level of science, and this is not always clear for a consumer. As part of the Framework, Health Canada is examining how these products would be classified, how health claims would be approved, and what would be the right set of tools for oversight. Throughout the development of the Framework, Health Canada will continue to inform the FDA and stakeholders on discussions about the future regulation of self-care products. This includes discussions on key issues being examined and policy proposals under development.	**June 2016 – March 2017**

Work stream C	Alignment of Good Manufacturing Practices for Sunscreens

Department/Agency	United States	Canada
		Health Canada

Planned initiatives and sub-deliverables	Date
Initiative A: On May 5th, 2016, stakeholders were invited to meet with U.S. and Canadian regulatory officials to identify and discuss new opportunities for regulatory cooperation under the RCC initiative. One of the stakeholder concerns brought forth in this session was quarantine and re-testing for products that go across the border, citing that Canadian requirements are duplicative and costly to industry. Therefore, Canada will examine its current legislation for the importation of sunscreens in their jurisdiction and explore opportunities for possible alignment of practices.	**June 2016 – December 2017**