

<b>Regulatory area to be addressed</b>	<p><b><u>Over-the-Counter Products</u></b></p> <p>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.</p>
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<b>Work stream A</b>	<b>Cooperation on Sunscreens</b>
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Department/Agency	 <b>United States</b>	 <b>Canada</b>
	U.S. Food and Drug Administration	Health Canada

Planned initiatives and sub-deliverables	Date
<p>On November 26, 2014, President Obama signed the Sunscreen Innovation Act 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. FDA will draft and finalize a guidance on sunscreens which will describe the safety and efficacy requirements that each sunscreen ingredient will need to meet in order to be included in the OTC sunscreen monograph.</p> <p>Under the 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).</p>	
<ul style="list-style-type: none"> <li>FDA and Health Canada will coordinate and discuss relevant sunscreen policies in Canada and the U.S.</li> </ul>	Summer 2015
<ul style="list-style-type: none"> <li>Health Canada will publish what was heard during the CHP Framework consultation and next steps, including any deliverables related to sunscreens</li> </ul>	August 2015
<ul style="list-style-type: none"> <li>FDA will publish a Draft Guidance for Industry on Sunscreens and solicit comments from stakeholders</li> </ul>	Fall 2015
<ul style="list-style-type: none"> <li>FDA will issue a Final Guidance on Sunscreens</li> </ul>	Late 2016



<b>Work stream B</b>	<p>The Framework seeks to modernize the oversight of consumer health products (i.e. self-care) while continuing to ensure that Canadians have access to safe and effective products. As part of this modernization, Health Canada is establishing a consistent and aligned approach to the regulation of health products intended for consumer use (cosmetics, disinfectants, natural health products (NHPs) or dietary supplements as they are referred to in the U.S., and non-prescription drug products). This includes addressing issues raised by stakeholders related to product classification.</p> <p>One of the principles underlying the Framework is international alignment. Health Canada is focused on alignment of outcomes rather than processes. As we learned from the first phase of RCC during the creation of the joint monograph on anti-histamines, alignment of process proved to be challenging given the differences in Canada and US regulatory systems.</p> <p>This Framework was posted for public consultation on November 27, 2014 for a 90-day period.</p>
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Department/Agency	 United States	 Canada
		Health Canada

<b>Planned initiatives and sub-deliverables</b>		<b>Date</b>
<b>Initiative A: Consumer Health Products Framework Consultation</b>		<b>November 2014 - February 2015</b>
	<p>On January 29, 2015, Health Canada hosted a webinar on the Consumer Health Products Framework consisting of an overview of the Framework and question and answer session. During the webinar there was discussion on the proposed changes to Health Canada’s monograph system and the Department’s ongoing work on sunscreen products.</p> <p>Health Canada also held four additional webinars with industry stakeholders covering the cosmetics, non-prescription drug, natural health product, and disinfectant industries. Further, during the period of November to February, there were discussions with industry associations on the Framework.</p>	

<b>Initiative B: Consumer Health Products Framework Action Plan</b>		<b>August 2015</b>
	Health Canada will be publishing a document summarizing what was heard during the consultations and next steps including deliverables. In the period leading up to the publication of the action plan, there will be ongoing discussions with the cosmetics, non-prescription drug, natural health product, and disinfectant industries through bilateral meetings as well as presentations and discussions at the industry associations' annual membership events.	
<b>Initiative C: Monograph System</b>		<b>January 2015 – March 2017</b>
	<p>Health Canada's Consumer Health Products Framework includes a proposal to create new regulations for non-prescription drugs that will help create a more flexible, responsive regulatory system that enables proportional oversight (i.e. requirements will be proportional to the risk-benefit-uncertainty profile of a product) . Part of this flexibility will come from the new authorities in the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) (e.g., incorporation by reference) which will be used to incorporate lists of documents such as product, class or substance-specific monographs, allowing for more efficient product approval through the use of compendia. This will allow Health Canada to establish a compendium of monographs that would provide an efficient means to seek approval for products that follow a monograph. Regulations supporting the monograph system are not expected to be implemented before 2017.</p> <p>As FDA is also looking at their monograph system in the context of the Sunscreen Innovation Act, Health Canada will share with FDA its work on the monograph system as Health Canada develops its regulations.</p>	