Regulatory area to be addressed	**Veterinary Drugs** Health Canada's Veterinary Drugs Directorate and the U.S. Food and Drug Administration's Center for Veterinary Medicine will coordinate their respective submission and review processes for veterinary drug applications to enable simultaneous product reviews with a view to simultaneous product availability. They will coordinate standards development and assessment activities pertaining to the pre-market evaluation of veterinary drugs, as appropriate. Further work in this area will also explore the availability of electronic templates that could be used to submit veterinary drug applications.

Work stream	Through a three-pronged approach that incorporates stakeholder feedback through regular engagement (e.g. bilateral meetings with the Canadian Animal Health Products Regulatory Advisory Committee or meetings with the Animal Health Institute), the U.S. FDA and Health Canada will expand upon their experience: - by simultaneously reviewing a broader variety of veterinary drug applications, - by collecting and focusing stakeholder needs to determine high benefit criteria for the selection of veterinary drugs for simultaneous review, and - by enabling more expeditious review of applications through electronic media toward earlier market entry.

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

Planned initiatives and sub-deliverables		**Date**
Initiative A - Pursue and build on the work accomplished under the initial Joint Action Plan, notably by expanding simultaneous reviews to supplemental veterinary drug applications.		**March 2015 –March 2017**
	• Continue to conduct simultaneous reviews of new applications for veterinary drugs	ongoing
	• Start conducting simultaneous review of supplemental veterinary drug applications	March 2015 start
	• Start conducting simultaneous review of applications for veterinary drugs for minor species (including fish health products)	March 2015 start
	• Conduct a strengths-weaknesses review of the initiative, to further refine the approach as necessary	June 2016

Initiative B - Develop and document an application procedure to help promote transparency and predictability of the simultaneous review process for interested applicants, with set criteria for applications that are conducive to and would benefit from the process.		**March 2015 –March 2017**
	• Share with stakeholders document outlying application procedure and proposed criteria for simultaneous review process	September 2016
	• Hold stakeholder consultations to discuss criteria for identifying veterinary drug applications that would most benefit from the simultaneous review process	October 2016
	• Establish a set of criteria for new veterinary drug applications, as to their acceptability into the RCC simultaneous review stream, taking into consideration relevant and practicable ideas derived from (1) stakeholder comments raised during the September 2016 session, (2) industry areas of interest, and (3) lessons learned from first phase of RCC and resources constraints	March 2017
	• Establish a set of criteria for supplemental veterinary drug applications, as to their acceptability into the RCC simultaneous review stream, taking into consideration relevant and practicable ideas derived from (1) stakeholder comments raised during the September 2016 session, (2) industry areas of interest, and (3) lessons learned from first phase of RCC and resources constraints	March 2017
Initiative C - Explore the expanded use of electronic means such as electronic templates to help streamline the preparation and submission of simultaneous applications.		**March 2015 – March 2017**
	• Jointly review the feasibility of Health Canada adopting the current FDA electronic submission templates and look into preliminary feasibility and financial assessment of expanding their use to Health Canada	December 2016