2019-2020 RCC Work Plan: Veterinary Drugs

Canadian Department: Health Canada
U.S. Department/Agency: Department of Health and Human Services, Food and Drug Administration (FDA)

Regulatory Cooperation Statement: The FDA and Health Canada will continue to coordinate their respective submission and review processes for veterinary drug applications to enable simultaneous product reviews. Further work in this area will also explore the expansion of Simultaneous Review to generic animal drug applications.

Work Plan:

Initiative	**Desired outcome(s)**	**Activities**	**Reporting**
Build on the work accomplished under the RCC Joint Forward Plan by exploring expansion of simultaneous reviews to generic animal drug applications	- Conduct simultaneous reviews of generic animal drug applications - Improve animal drug availability in the United States and Canada	- Consult and share information with industry stakeholders including the generic animal drug industry (March – April, 2020)	
		- Exchange information on the regulatory frameworks and scientific review processes for generic animal drugs in each jurisdiction between agencies (Summer, 2019)	**Fall 2019:** Completed **Final update: Health Canada and the U.S. FDA exchanged this information in a series of bilateral meetings in summer, 2019.**
		- Define criteria for regulatory authorities to identify candidate generic animal drug applications for simultaneous review (January – March, 2020)	
		- Identify a simultaneous review of a generic animal drug application (September, 2020)	
		- Discuss lessons learned from pilot simultaneous reviews of a generic animal drug and any next steps (2021)	