

# Seresto®

## Stewardship Program



On July 13, 2023, Elanco Animal Health Incorporated and the Environmental Protection Agency (EPA) announced that the EPA, with support from the Food and Drug Administration (FDA), completed its comprehensive, multi-year review of the Seresto® flea and tick collar. EPA confirms continued registration of the collar. Comprehensive data affirms the safety profile of Seresto.

Following the comprehensive review, Elanco and EPA developed a stewardship program that Elanco will implement as a leader in the collar category.



### The program includes:

**Enhanced data collection for adverse event (AE) reports** – Elanco is implementing additional training for relevant personnel to enhance data collection for AE reporting to ensure best efforts to capture patient information, such as pre-existing medical conditions, medications concomitantly administered, previous uneventful history with the product and patient health status where an attending veterinarian is involved.

**Continued annual enhanced reporting of Seresto AE data** – Elanco’s existing pharmacovigilance and regulatory affairs teams will report AE and sales data for Seresto to EPA using standard agency templates on an annual basis, similar to what EPA requires for pet spot-on products.

**Outreach to the veterinary community** – Elanco will utilize existing relationships and digital tools to share information with the U.S. veterinary community around the benefits, as well as possible risks, associated with use of pesticides, including Seresto, and the importance of reporting adverse events.

**Review of the collar release mechanism** – Elanco will assess functionality of and potential modifications to the release mechanism to optimize performance. Analysis will be provided to EPA within one year.

**Separation of product registrations for dog and cat** – Elanco has established a new registration for Seresto Cat. The existing EPA registration will remain for Seresto Dog. This change will allow for more granular adverse event evaluation.

**Updates to package insert language** – Elanco has created species specific product labels (dog and cat) and updated package insert language to include additional information on potential adverse events. Existing Seresto inventory to be sold with no expected commercial disruption or material financial impact related to the change.

**Five-year registration review to ensure stewardship program actions support the continued safe use of Seresto** – For the next five years, utilizing its existing pharmacovigilance and regulatory affairs teams, Elanco will submit an annual report to EPA, providing an update on stewardship efforts and an analysis of safety information collected the preceding year to ensure these stewardship efforts support the continued safe use of Seresto. Elanco will complete a renewal process near the end of this period.

