March 27, 2026

Elanco US Inc
Attention: Brett McKusick, BA, DVM, MS, PhD
Senior Director, Global Regulatory Affairs
450 Elanco Circle
Indianapolis, IN 46221

Re: Emergency Use Authorization 006662 Revised Fact Sheet

Dear Dr. McKusick:

Please refer to your Emergency Use Authorization (EUA) for the emergency use of Credelio (lotilaner) chewable tablets for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, issued on October 24, 2025, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

We have updated the authorized "Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio (lotilaner) Chewable Tablets for New World Screwworm (NWS)" to better reflect within the Fact Sheet certain conditions of the authorization (e.g., information for veterinarians), expanded the information provided on adverse event reporting, and made editorial improvements for clarity. The updated authorized "Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio (lotilaner) Chewable Tablets for New World Screwworm (NWS)" is attached to this correspondence for your reference with the new revision date of 03/27/2026.

If you submit correspondence relating to this letter, your correspondence should reference the date and EUA submission number identified in this letter. For correspondence relating to this letter, or if you have questions or need assistance with the product development process or project updates, contact your project manager. If you do not know who your project manager is, send an email to AskONAPEPM@fda.hhs.gov.

Sincerely,

{see appended electronic signature page}
Matthew A. Lucia, DVM
Director
Office of New Animal Product Evaluation
Center for Veterinary Medicine

Enclosure:
Revised Fact Sheet

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov