



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 19-05

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron E. Rippke
Director

SUBJECT: Name Change for *In Vitro* Diagnostics (Test Kits) Intended to Detect Canine or Feline Heartworm Antigen.

I. PURPOSE

The intended purpose for this Notice is to inform licensees, permittees, and applicants of a change in the True Name of applicable products.

II. BACKGROUND

The CVB is changing the True Name of products named “Canine Heartworm Antigen Test Kit” and “Feline Heartworm Antigen Test Kit” to “Heartworm Antigen Test Kit”. The product claim(s), as specified on labeling, will inform the user of the kit’s intention regarding test sample origin.

III. ACTION (or POLICY)

The CVB will use the new nomenclature for products in the prelicense stage. For licensed and permitted products, revise Outlines of Production and labeling. All affected firms must comply within two years of the date of this notice.

The CVB will reissue a new license or permit within 60 days of the date of the notice. It is not necessary for the firm to make a submission to request reissuance of a new license with an updated True Name.

IV. IMPLEMENTATION/APPLICABILITY

This action is effective immediately.