



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE 18-03

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

**FROM:** Byron E. Rippke  
Director

**SUBJECT:** Changes in True Names Based on Accepted Nomenclature

### I. PURPOSE

The Center for Veterinary Biologics (CVB) recognizes that names of organisms may change over time due to taxonomic investigations and subsequent reclassification. The CVB uses this Notice to inform firms of the CVB process for approving changes in product True Names.

### II. POLICY

The CVB will consider requests for changes in product True Names based on acceptance of the new nomenclature by the appropriate organization(s) and by the scientific community over a reasonable period of time (e.g., usage via publication in applicable, reputable journals). In the submission, the firm should include such justification. Regarding appropriate organizations, for bacterial agents, see the List of Prokaryotic Names with Standing in Nomenclature site: <http://www.bacterio.net/index.html>. The International Committee on Taxonomy of Viruses site provides official names of viruses: <http://www.ictvonline.org/virusTaxonomy.asp>. For animal parasites, see the International Commission on Zoological Nomenclature site: <http://iczn.org/content/about-zoobank>. For other organisms, regarding evidence of acceptance of the new nomenclature by pertinent organizations and the scientific community, the firm should submit relevant publications and/or a list of references. The CVB may also initiate the True Name change as deemed necessary.

Upon CVB approval, the CVB issues a Notice informing all firms of the change in the True Name. The CVB will use the new nomenclature for products in prelicense stage. For licensed products, the CVB requires revision of the Outlines of Production and labels. All affected firms must comply within within 2 years. The firm may opt to use both genus names, e.g., *Avibacterium (Haemophilus) paragallinarum*, on labels for up to 2 years.

The CVB will issue a new license within 60 days of approval of the new True Name, as documented by issuance of the Notice. It is not necessary for the firm to make a submission to request issuance of a new license with an updated True Name.

Firms seeking detailed guidance may contact CVB-Policy, Evaluation, and Licensing or their assigned Reviewer.

### III. IMPLEMENTATION/ APPLICABILITY

Implementation is effective immediately.