



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 19-04

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

**FROM:** Byron E. Rippke  
Director

**SUBJECT:** Name Change for Biologics Containing *Mycobacterium avium* subspecies *paratuberculosis*, formerly *Mycobacterium paratuberculosis*

### I. PURPOSE

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

### II. BACKGROUND

*Mycobacterium paratuberculosis* has been renamed *Mycobacterium avium* subspecies *paratuberculosis* as a result of taxonomic investigations. The scientific community has endorsed this new name and it is included in the List of Prokaryotic Names with Standing in Nomenclature: See <http://www.bacterio.net/index.html>. Since the CVB uses standard nomenclature when reasonably possible, CVB-assigned True Names for products containing this organism will now include "Mycobacterium Avium Subspecies Paratuberculosis."

### III. ACTION (or POLICY)

The CVB will use the new nomenclature for products in the prelicense stage. For licensed and permitted products, Outlines of Production and labelling should be revised. 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.