



June 13, 2006

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-16

Animal and Plant
Health Inspection
Service

Subject: True Name Change for Canine Vaccines with Bacterins Containing
Leptospira

Veterinary Services

Center for Veterinary
Biologics

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
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I. PURPOSE

This notice informs licensees, permittees, and applicants of a change in the True Name of certain products containing *Leptospira* antigen intended for use in canines. All True Names will identify each *Leptospira* serovar contained in these products.

II. BACKGROUND

Typically, the True Name for bacterial biological products identifies the genus and species (or equivalent taxonomic identifier) for each component. For example, *Leptospira* bacterins typically include the genus and serovar(s), e.g., *Leptospira Canicola-Icterohaemorrhagiae* Bacterin. An exception to this naming convention was made for *Leptospira*-containing vaccines with bacterins intended for use in dogs, because they invariably contained *L. canicola* and *L. icterohaemorrhagiae*. Thus, a product with a shortened True Name, e.g., Canine Coronavirus Vaccine-*Leptospira* Bacterin, was considered acceptable to accurately describe the product.

The need for additional *Leptospira* serovars in canine products has emerged in recent years, and manufacturers have responded by producing *Leptospira*-containing vaccines with bacterins that contain various combinations of *Leptospira* serovars. Thus, a True Name that does not specify the serovar(s) is no longer considered sufficiently descriptive.

III. ACTION

All licenses for products containing *Leptospira* serovars issued subsequent to October 1, 2006, will bear a True Name identifying each *Leptospira* serovar in the product. The Center for Veterinary Biologics will reissue the Product Licenses for currently licensed products that do not include each *Leptospira* serovar in the True Name. True Names should be revised in Outlines of Production and labels no later than October 1, 2008.



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In the case of products packaged in small containers for which the expanded True Name may be problematic due to space constraints on the label, licensees and permittees may request permission to use an abbreviated True Name. In such cases, the reissued product license will bear the acceptable abbreviated True Name in addition to the complete True Name. Abbreviated True Name will be used only on small container labels for products that are marketed with additional labeling that specifies the complete True Name. The complete True Name will continue to be required on all other labeling material (e.g. cartons, enclosures).

The acceptable abbreviations for the four *Leptospira* serovars commonly found in canine products are:

<u>Name</u>	<u>Abbreviation</u>
<i>Leptospira canicola</i>	LCAN
<i>Leptospira grippotyphosa</i>	LGRIP
<i>Leptospira icterohaemorrhagiae</i>	LICT
<i>Leptospira pomona</i>	LPOM

Example:

Complete True Name: Canine Coronavirus-Parvovirus Vaccine, Killed Virus, *Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona* Bacterin

Abbreviated True Name: Canine Coronavirus-Parvovirus Vaccine, Killed Virus, LCAN-LGRIP-LICT-LPOM Bacterin

/s/ Byron E. Rippke for

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