



February 24, 2005

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-06

Animal and Plant
Health Inspection
Service

Subject: Requirements for Addition of *Leptospira bratislava* in Canine Bacterins

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

Center for Veterinary
Biologics

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I. PURPOSE

This notice informs licensees, permittees, and applicants of current Center for Veterinary Biologics (CVB) policy regarding requirements for the addition of *Leptospira interrogans* serovar bratislava antigen to current canine leptospira-containing bacterins.

II. BACKGROUND

Recent inquiries regarding the of addition of *Leptospira interrogans* serovar bratislava antigen to current canine leptospira-containing bacterins have necessitated that CVB establish a consistent policy on this issue and communicate that policy to the veterinary biologics industry.

Although there is limited evidence that *Leptospira interrogans* serovar bratislava may be a pathogen of dogs in the United States, the information in published scientific literature is deemed by CVB to be insufficient to warrant addition of the *L. bratislava* antigen to canine leptospira-containing bacterins. Nearly all of the current data supporting the theory that *L. bratislava* is a significant canine pathogen in the United States are based on serology which is not considered to be a definitive indication of disease etiology for leptospirosis. Despite publications demonstrating the ability to isolate the organism from naturally and experimentally infected animals, only a single case of isolation from a clinically ill dog in the United States exists in the published literature. Until evidence acceptable to CVB is published in the scientific literature that establishes *Leptospira interrogans* serovar bratislava as a significant pathogen of dogs in the United States, firms will need to provide that evidence before inclusion of the *L. bratislava* antigen in licensed leptospira-containing bacterins will be considered.

III. POLICY

The following is the minimum evidence required for inclusion of the *L. bratislava* antigen in licensed leptospira-containing bacterins.

1. Proof of disease etiology confirmed by isolation of the organism from a minimum of 10 dogs demonstrating clinical signs consistent with leptospirosis. The animals must originate from outbreaks that are not epidemiologically linked.



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2. Isolations must be conducted by a minimum of two independent laboratories.
3. Culture identities must be confirmed in a manner acceptable to CVB.
4. The identity of all bacteria, viruses, and other disease agents isolated from the clinically ill animals must be reported so that the possibility of other etiologies of the disease, or the possibility of synergistic infections, can be evaluated.
5. Although no acceptable Leptospiral identification methods other than culture currently exist which are capable of differentiating serovars of *Leptospira*, such methods may be developed in the future (e.g., polymerase chain reaction). Such methods may be used for proof of disease etiology **only if** the test method is validated in a manner acceptable to CVB. If test methods other than culture are used to prove disease etiology, then a minimum of 25 clinically affected dogs from outbreaks that are not epidemiologically linked will be required. The clinically ill animals must also be evaluated for the presence of other possible pathogens (see 4. above).
6. Serological evidence of infection alone will not be a sufficient indication of disease etiology.

/s/ Richard E. Hill, Jr.

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