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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 07-12

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Subject: Qualification of *Leptospira pomona* and *Leptospira canicola* Reference Bacterins for Products Intended for Use in Dogs

To: VS Management Team (VSMT)
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

I. PURPOSE

The purpose of this notice is to inform interested parties of the procedures that may be used to qualify Reference Bacterins for *Leptospira pomona* and *Leptospira canicola* that may be used to test products intended for use in dogs. It also announces the availability of Standard Reference Bacterins distributed by the Center for Veterinary Biologics (CVB). These Standard Reference Bacterins are available to all licensees, permittees, and applicants to use under specified conditions in the *in vitro* potency assays described in Supplemental Assay Methods (SAM) 624 and 625. The availability of these standard references does not preclude the use of a suitably qualified alternative reference developed by the licensee.

II. BACKGROUND

The codified potency tests for *Leptospira Pomona* Bacterin and *Leptospira Canicola* Bacterin are hamster vaccination-challenge assays described in Title 9, Code of Federal Regulations (9 CFR), Parts 113.101 and 113.103, respectively. These tests have been targeted by the CVB for replacement as part of the CVB's ongoing commitment to refine, reduce, and replace animal testing. Enzyme-linked immunosorbent assays (ELISAs) that quantify protective antigens of *Leptospira pomona* and *Leptospira canicola* have been developed by the CVB and are described in SAM 624 and 625, respectively. The ELISAs require the use of a suitably qualified reference bacterin. Qualifying a new reference bacterin typically involves a demonstration that the reference is acceptably efficacious in a host animal vaccination-challenge model. A surrogate animal model may be used in lieu of host animal studies to qualify a reference, provided that the surrogate animal model is deemed to be an acceptable indicator of efficacy in the host animal.

The CVB conducted studies to determine whether the codified hamster potency test is a suitable surrogate to evaluate the efficacy of *L. pomona* and *L. canicola* in dogs. Serials formulated to meet only the minimum potency requirements in hamsters were found to be acceptably efficacious in dogs (data available upon request). These data give the CVB confidence that the hamster test can be used as a surrogate for host animal vaccination-

challenge to qualify references for *L. pomona* and *L. canicola* bacterins for canine products (i.e., serials passing the hamster potency test will also be efficacious in dogs). Thus, the CVB will consider, under the conditions described in Section III below, references qualified by the hamster potency test.

To further facilitate conversion to *in vitro* testing, the CVB has qualified the following Standard Reference Bacterins for use with SAM 624 or 625:

- IRP 524 (05): *Leptospira Pomona* Standard Reference Bacterin (Lot NRS042805LP)
- IRP 555 (07): *Leptospira Canicola* Standard Reference Bacterin (Lot 82518)

These Standard Reference Bacterins are non-adjuvanted preparations, which may be suitable to serve as working references for certain *Leptospira* Bacterins labeled for use in dogs.

III. GUIDANCE

Under 9CFR 113.4, licensees and permittees must request an exemption to the codified hamster potency tests in order to use the ELISAs. Please refer to Section III of Center for Veterinary Biologics Notice 07-02 for exemptions to codified potency tests for *Leptospira grippotyphosa* and *L. icterohaemorrhagiae* (9CFR 113.102 and 113.104). The procedures, required supporting data, and applicability for exemption described therein also apply to requests for exemptions from 9CFR 113.101 and/or 9CFR 113.103.

IV. ACTION

Licensees, permittees, and applicants wishing to obtain *Leptospira Pomona* Standard Reference Bacterin IRP 524 (05) and/or *Leptospira Canicola* Standard Reference Bacterin IRP 555 (07) should make a request to the CVB according to the procedures established in Veterinary Services Memorandum 800.97. The Memorandum, which includes a copy of the request form, may be obtained from the CVB website (www.aphis.usda.gov/vs/cvb) or by contacting the CVB.

SAMs 624 and 625 are also available on the CVB website or by contacting the CVB.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics