



CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 15-04

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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TO: Biologics Licensees, Permittees, and Applicants
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FROM: Byron E. Rippke
CVB Director

**BYRON
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SUBJECT: Nomenclature and Level of Identification Required for *Leptospira* Master Seed Bacteria and Challenge Cultures.

I. PURPOSE

The purpose of this notice is to inform interested parties of the appropriate nomenclature and level of identification required for a *Leptospira* Master Seed and challenge. True Names for the products will remain unchanged.

II. BACKGROUND

Leptospirosis is caused by spirochetes belonging to the genus *Leptospira*, which comprises both saprophytic and pathogenic species. Traditional classification specified that all saprophytic species are under *Leptospira biflexa*, while *L. interrogans* included all pathogenic species. The currently used genetically based classification indicates that there are at least 19 species (13 pathogenic and six saprophytic) identified through DNA hybridization analyses. Seven of these species, *L. interrogans*, *L. borgpetersenii*, *L. santarosai*, *L. noguchii*, *L. weilli*, *L. kirschneri* and *L. alexanderi*, are the main agents of leptospirosis. More specific identification of Master Seed and challenge will help resolve technical difficulties when moving to *in vitro* testing.

III. ACTION

A. Master Seed

1. The genus, species, and serogroup should be indicated in Section I of the Outline of Production when describing the Master Seed of any product containing *Leptospira canicola*, *grippotyphosa*, *icterohaemorrhagiae*, and *pomona* fractions. Identification of the serovar and strain is preferred but not required for these Master Seeds.

Example: The isolate is *Leptospira interrogans* Serogroup Icterohaemorrhagiae. Restriction enzyme analysis indicates it is serovar copenhageni, RGA, or monymusk, but current technical limitations prevent more specific identification.

2. The genus, species, and serovar should be indicated for products containing *Leptospira hardjo* and *Leptospira bratislava* fractions. Identification of the strain is preferred but not required for these Master Seeds.

Example: The isolate is *Leptospira borgpetersenii* serovar hardjo-bovis strain 93U.

3. New Master Seed Bacteria (MSB) must be identified to the serogroup or serovar level as indicated above. For existing approved MSB, this information should be added to the Outline of Production. Working seeds may be used for identification. Firms should contact their reviewer for specific guidance.

B. Challenge

A biological product containing *Leptospira* fractions that is potency tested through a hamster vaccination-challenge assay must have the challenge used in the potency assay indicated in Section V.C. of the Outline Production in accordance with VS Memorandum 800.206. Likewise, the challenge used in efficacy studies for products containing *Leptospira* fractions must be indicated.

1. The genus, species, and serogroup should be indicated for challenge used to test products containing *Leptospira* Serogroups Canicola, Grippotyphosa, Icterohaemorrhagiae, and Pomona. Identification of the serovar and strain for the challenge is also preferred but not required.
2. Nomenclature Changes – The CVB has adopted the following nomenclature for the *Leptospira* challenges supplied to stakeholders for potency tests codified in 9 CFR 113.101 – 113.104:

Current designation	Proposed designation
<i>Leptospira canicola</i>	<i>Leptospira interrogans</i> Serogroup Canicola
<i>Leptospira grippotyphosa</i>	<i>Leptospira kirschneri</i> Serogroup Grippotyphosa
<i>Leptospira icterohaemorrhagiae</i>	<i>Leptospira interrogans</i> Serogroup Icterohaemorrhagiae
<i>Leptospira pomona</i>	<i>Leptospira interrogans</i> Serogroup Pomona

The CVB will revise this nomenclature in SAMs, reagent data sheets, and other documents.

3. The genus, species, and serovar should be indicated for challenge used to test products containing *Leptospira hardjo* and *Leptospira bratislava* fractions. Identification of the strain is also preferred but not required.

IV. IMPLEMENTATION/ APPLICABILITY

Annual review of Outlines of Production is required as per 9 CFR 114.8(d). As this occurs, Section I and Section V should be updated to reflect the current naming convention. It is expected that documents will be in compliance with the nomenclature update within 18 months of publication of this notice. If additional time is needed, firms should request additional time from their reviewer prior to the deadline and supply a time line for their compliance.