November 4, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.86

Subject: Exemption from Mycoplasma Testing Under 9 CFR 113.200(c)(3)

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

I. PURPOSE

This memorandum clarifies Center for Veterinary Biologics (CVB) policy for obtaining an exemption to the requirement for testing inactivated viral vaccines for mycoplasma contamination.

II. CANCELLATION

This memorandum cancels Veterinary Biologics Memorandum No. 800.86 dated January 4, 1996.

III. BACKGROUND

Under 9 CFR 113.200(c)(3), the harvest fluids used in the production of killed virus vaccines must be tested for mycoplasma contamination according to 9 CFR 113.28 prior to adding the killing agent. However, the regulations provide for the granting of an exemption to this requirement if the licensee or permittee demonstrates "that the agent used to kill the vaccine virus would also kill mycoplasma." This memorandum clarifies CVB policy concerning the exemption from mycoplasma testing for inactivated viral vaccines. Note that this exemption only applies to the testing of vaccine virus prior to adding the killing agent and not to the testing of Master Seeds, Master Cell Stocks, primary cells, or ingredients of animal origin.

IV. POLICY

To obtain an exemption to the requirement for testing inactivated viral vaccines for mycoplasma contamination:

A. Validate the Inactivation Process

The licensee or permittee must show that the procedure described in the Outline of Production for vaccine virus inactivation will also inactivate mycoplasma.

B. Verify Proper Performance in the Outline of Production

The Outline of Production must indicate an acceptable method that the firm will use to verify the proper performance of the inactivation procedure. The method indicated in the Outline of Production can be the mandatory in-process test for vaccine virus inactivation if the licensee or permittee has submitted data indicating that mycoplasma are at least as sensitive as the vaccine virus to the inactivation procedure.

C. Submit Protocols

Before initiating studies to establish the appropriateness of the inactivation procedure and the verification method, licensees, permittees, and applicants should submit protocols to CVB for review and comment.

1. *Indicate Mycoplasma Species* - The protocols should indicate the species of mycoplasma to be employed.

2. *Mycoplasma Species to Use* - The mycoplasma species selected should include species recognized as common cell culture contaminants as well as those found in the animal(s) for which the product is intended.

D. Document Exemptions

If CVB grants an exemption from mycoplasma testing for a product under 9 CFR 113.200(c)(3), Part V of the Outline of Production for the product should indicate the date the exemption was granted.

/s/ Thomas E. Walton for

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