October 18, 2007

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.58

TO: VS Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: John R. Clifford /s/ John R. Clifford
Deputy Administrator

SUBJECT: Sublicensing of Veterinary Biological Products

I. PURPOSE

This memorandum establishes guidance for the sublicensing of a veterinary biological product from one licensed veterinary biologics establishment to another biologics establishment.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.58, dated November 4, 1999.

III. BACKGROUND

Sublicensing occurs when a licensed establishment transfers the technology to produce a currently licensed product to another (receiving) establishment. The receiving establishment, in order to produce and market this product, must have or obtain an establishment license and obtain a product license according Title 9, Code of Federal Regulations, (9 CFR) Part 102.

IV. PROCEDURES

A. Licensing Requirements - The firm (applicant) seeking to produce and market a product through sublicensing must submit the following items to the Center for Veterinary Biologics-Policy, Evaluation, and Licensing (CVB-PEL).

1. *Application for an Establishment License* – An application for United States Veterinary Biologics Establishment License (APHIS Form 2001) and supporting materials according to 9 CFR 102.3. (Note: This does not apply if the firm already has an establishment license.)

2. *Application for Product License* – An application for United States Veterinary Biological Product License (APHIS Form 2003).

3. *Permission to Use Previously Filed Data* – Documented permission from the licensed firm transferring the technology for the applicant to support the current application using all requisite research, field trial, and production data submitted to CVB-PEL when the product was previously licensed.

4. *Request to Transfer Material* – A request to CVB-PEL for approval to bring necessary production materials into the applicant's production facility.

5. *Evidence of Technology Transfer* – Documented evidence from the licensed firm that the applicant has been provided all the necessary technical information and assistance that is needed to produce the product in the same manner as it was produced by the licensed firm.

6. *New or Amended Facilities Documents* – New or amended plot plan, blueprints, and legends of the applicant's production facilities, as applicable, in accordance with 9 CFR 108.

7. *Outline of Production* – An Outline of Production prepared in accordance with 9 CFR 114.8 and 114.9. For vaccines, bacterins, antigens, and toxoids, see also Veterinary Services (VS) Memorandum 800.206 for guidance. All essential procedures must be identical to those of the licensed firm.

8. *Supporting Data* – The CVB may request additional supporting data, generated by the license applicant, on a case-by-case basis.

    a. Tests for purity, identity, and virulence of Master Seeds and Master Cell Stocks. These tests will be required if new Master Seed or Master Cell Stocks are prepared by the license applicant, even though they are derived from the stocks provided by the licensed firm transferring the technology. Additional testing may be required on previously approved Master Seeds and Cell Stocks if the original testing does not meet all current testing requirements.

    b. An efficacy (immunogenicity) study. The license applicant may be required to conduct an efficacy study if the original efficacy study does not meet all current efficacy requirements; see VS Memorandum 800.202. Efficacy studies will be required of all applicants sublicensing a Rabies Vaccine.

9. *Test Reports* – Veterinary Biologics Production and Test Reports (APHIS Forms 2008), prepared according to Veterinary Services Memorandum No. 800.53, for up to three consecutive satisfactory serials of the product.

10. *Labels* – Labels prepared according to 9 CFR 112. All directions for use, warnings, or cautions from labels in use by the original licensee or any changes made by the applicant must be supported by valid data.

B. Prelicense Testing - Before issuing a license, the CVB may conduct confirmatory testing of Seeds, Cells, and production serials, as appropriate.