

October 1, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.64

Subject: Preparation of Experimental Products at Licensed Establishments
To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum provides guidance for obtaining permission to prepare an experimental veterinary biological product in production facilities of a licensed establishment according to 9 CFR 103.1.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.64, dated July 31, 1985.

III. PROCEDURES

A. Request Permission

Licensees should submit requests for permission to prepare an experimental veterinary biological product in production facilities of a licensed establishment to:

Center for Veterinary Biologics
Licensing and Policy Development
510 South 17th Street, Suite 104
Ames, IA 50010-8197

Requests should include the supporting information specified in 9 CFR 103.1.

B. Limit Production

Center for Veterinary Biologics-Licensing and Policy Development will limit the quantity of experimental product to be prepared to the amount needed to fulfill the purpose of the experiment.

C. Revise Facility Documents

For continued production of the product in the licensed establishment, the Center for Veterinary Biologics will require the Licensee to submit revised blueprint legends with a copy of the letter received from CVB-LPD authorizing the production of the experimental product in licensed production facilities and obtain CVB-IC approval as provided in 9 CFR 108.6. Revisions of blueprint legends should be sent to:

Center for Veterinary Biologics
Inspection and Compliance
510 South 17th Street, Suite 104
Ames, IA 50010-8197

/s/

Alfonso Torres
Deputy Administrator
Veterinary Services