

July 29, 2002

VETERINARY SERVICES MEMORANDUM NO. 800.100

Subject: Exemption from Using Heat or Ionizing Radiation to Treat Equine Plasma Used in Manufacturing Plasma Products for Oral or Parenteral Administration to Horses Under 9 CFR 113.450(e)(1) and Exemption from the Mouse Safety Test Under 9 CFR 113.450 (i)

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

I. PURPOSE

This memorandum clarifies Center for Veterinary Biologics policy for obtaining an exemption to the requirements of 9 CFR 113.450 concerning treatment and processing procedures for plasma products that are administered to horses orally or parenterally.

II. BACKGROUND

APHIS has published the general requirements for antibody products in 9 CFR 113.450. This regulation requires all blood derivatives used in the production of antibody products for the treatment of horses to be processed by heating at 58-59° C for 60 minutes or treated with 2.5 megarads of ionizing radiation in order to inactivate potential contaminating microorganisms. However, treatment by heat or ionizing radiation may damage plasma and make it unacceptable for use.

Under 9 CFR 113.4, APHIS may grant an exemption to the required treatment if it can be demonstrated that another procedure for preventing potential contamination is at least as effective as the procedure(s) specified in the regulation. However, because equally effective treatment methods are not available, this memorandum specifies procedures that may be used to mitigate the risk of infecting horses with contaminated product and provide the basis for an exemption to the treatment(s) specified in the regulation.

III. POLICY

To obtain an exemption to the requirement that equine plasma used in manufacturing veterinary biologics be processed by heating or treating with ionizing radiation:

A. Test Donor Horses for Equine Infectious Anemia (EIA)

In part I of the filed Outline of Production include a provision to test donor horses for EIA before first use and at the time of each donation of plasma. Tests must be performed at a laboratory approved by APHIS and horses that test positive for EIA may not be used for the donation of plasma for use in manufacturing veterinary biologics.

B. Report Test Results on APHIS Form 2008

Plasma may not be used in manufacturing veterinary biologics for oral or parenteral administration to horses before the tests for EIA are completed and the results are known. EIA test results for each horse should be reported on APHIS Form 2008 submitted to CVB-IC for serial release.

C. Add Warning Statement to Labels

Add a label warning advising the user that the product has not been processed by heating or treating with ionizing radiation and may be capable of spreading disease.

IV. EXEMPTION TO MOUSE SAFETY TEST

Bulk or final container samples of plasma products for oral or parenteral administration to horses are exempted from the mouse safety test prescribed in 9 CFR 113.450 (i) if the procedures specified in section III. A-C. above have been followed.

/s/ W. Ron DeHaven

W. Ron DeHaven
Deputy Administrator
Veterinary Services