

November 9, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE 99-26

Subject: Alternative Safety Testing for Serial Release of Oral Antibody Products
To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

This notice informs licensees, permittees, and applicants that the Center for Veterinary Biologics will consider requests for the use of alternative safety test procedures for oral antibody products under 9 CFR 113.4.

Regulations in 9CFR 113.450(i), require bulk or final containers of each serial of antibody products be tested by 113.33(b). In this test, each of eight mice are to be injected subcutaneously or intraperitoneally with 0.5 ml of the product and observed for seven days. Some producers of oral antibody products have found this test to be unsatisfactory for use in the testing of their product for safety.

CVB will therefore consider the approval of alternative safety test procedures for oral antibody products to permit the use of a safety test where the product is administered orally to appropriate-aged animals of the same species for which the product is recommended. Firms requesting the use of such an alternative test procedure should describe the test in their Outline of Production for the product and provide adequate justification to support their request for this exemption.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics