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United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-05

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Richard E. Hill, Jr. */s/ Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

SUBJECT: Testing Exemptions for Antibody Product Donor Animals

I. PURPOSE

The purpose of this Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is in the process of reviewing regulations requiring testing as outlined in Title 9, Code of Federal Regulations (9 CFR), Part 113.450. This Notice responds to a resolution by the United States Animal Health Association that requests updating the testing required of antibody donor animals.

II. BACKGROUND

The 9 CFR 113.450 currently requires horses used for antibody production to be tested for dourine, glanders, piroplasmosis, brucellosis, and equine infectious anemia (EIA). Horses pastured or housed with no other species are not required to be retested annually for brucellosis. Annual retesting is required for EIA. Dourine and glanders have been eradicated from the United States for several decades. All imported horses must have negative test results for dourine, glanders, and piroplasmosis. Although the incidence of EIA has been greatly reduced, the disease has not been eradicated from the U.S. horse population.

Cattle are currently required to be tested for brucellosis and tuberculosis before use as antibody donors and must be retested annually. The annual retesting of steers has become a burden due to the false positive test results encountered and the costs associated with the false positive test results.

III. POLICY

The CVB will consider written requests for exemptions to the 9 CFR 113.450 testing requirements for the following named diseases for animals of specified species, origin, and maintenance, until the applicable 9 CFR regulations are revised.

A. Horses of United States residency are eligible for an exemption to 9 CFR 113.450(c)(2)(i)(B) dourine and glanders testing, contingent upon the continued lack of either disease in United States resident equines.

B. Non co-mingled steers originating from certified brucellosis-free herds located in Bovine Brucellosis Class Free States, having no diagnosed *Brucella abortus* in the State's wildlife, may be eligible for an exemption to the 9 CFR 113.450(c)(2)(iv) annual retesting for brucellosis. The steers must be maintained with no exposure to wildlife susceptible to brucellosis. An exemption to annual retesting for brucellosis is limited to steers used solely for products tested according to 113.450(e)(1).

C. Non co-mingled steers originating from a Tuberculosis Accredited Herd located in a Bovine Tuberculosis Accredited Free State, having no diagnosed bovine tuberculosis in the State's wildlife, may be eligible for an exemption to the 9 CFR 113.450(c)(2)(iv) annual retesting for tuberculosis. The steers must be maintained with no exposure to wildlife susceptible to tuberculosis. An exemption to annual retesting for tuberculosis is limited to steers used solely for products tested according to 113.450(e)(1).

Written requests for exemptions should be addressed to the Reviewer assigned to the establishment.

IV. IMPLEMENTATION/ APPLICABILITY

A statement of the applicable criteria for the exemption and the date of the letter granting the exemption shall be included in the Outline of Production, Section I.B. The date of implementation will be the date the Outline of Production revision is filed by APHIS.