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July 9, 2001

CENTER FOR VETERINARY BIOLOGICS NOTICE 01-07

Subject: Identification of Testing Methods for Detection of Extraneous Agents in Fetal Bovine Serum

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

I. PURPOSE

The purpose of this notice is to request information regarding how firms currently are meeting requirements for and providing results of extraneous agent testing of fetal bovine serum (FBS) in accordance with 9 CFR 113.53. Historically, this information has been determined by various methods and reported in variable formats. The Center for Veterinary Biologics (CVB) is interested in how the ingredients of animal origin are being tested and who actually conducts the testing. It is the intent of the CVB to gather this information for future policy decisions.

II. ACTION

Licensees and Permittees should update their information on extraneous agent testing of FBS to reflect current practices and provide an informational summary listing the test methods used by the firm to the CVB. The firm should also provide if testing is: 1) conducted by the firm, contract, or serum supplier; or 2) if Certificates of Analysis, firm bench records, internal Quality Assurance audits, Audits of contractors, or other forms of information from contractors or suppliers is offered as verification of extraneous agent for FBS.

The CVB requests that firms submit copies of this informational summary to the Center for Veterinary Biologics-Licensing and Policy Development before September 15, 2001.

Randall L. Levings
Director
Center for Veterinary Biologics