RESOLUTION NUMBER: 9 APPROVED

SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF CATTLE, BISON, AND CAMELIDS

SUBJECT MATTER: Importation of Fetal Bovine Serum

BACKGROUND INFORMATION:
Concerns about the current and expected future shortage of North American origin fetal bovine serum is leading to strong concern over importation of contaminating viruses including pestivirus in fetal bovine serum. Current testing is based on decades-old technology which does not adequately detect new and emerging viruses.

RESOLUTION:
The United States Animal Health Association strongly encourages the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to revise Title 9 Code of Federal Regulations Section 113.53 standards as they apply to fetal bovine serum testing to make changes requiring the use of appropriately sensitive technology and addressing country of origin labeling.

INTERIM RESPONSE:
The United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association (USAHA) and appreciates the opportunity to respond.

VS’ Center for Veterinary Biologics (CVB) has developed a group to work on determining which tests should be conducted and how the current rule should be amended. As per the request at the USAHA meeting, once industry subject matter experts have been identified, they will be invited to provide their perspective also. Additionally, the CVB is in the process of developing a working group with the biologics industry to gather information as to how they test Fetal Bovine Serum, and to gain a better understanding of testing the industry may be doing that is additional and/or outside of the current regulatory requirements.