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June 1, 2009

Dr. Richard E. Hill, Director
USDA APHIS Center for Veterinary Biologics
Animal and Plant Health Inspection Service
510 South 17th Street, Suite 104
Ames, IA 50010

RE: Draft No. 335 – Guidelines for Autogenous Biologics

Dear Dr. Hill:

The American Veterinary Medical Association (AVMA), consisting of over 78,000 members and representing approximately 85% of veterinarians in the U. S., is the largest veterinary medical association in the world. Established in 1863, to advance the science and art of veterinary medicine, the AVMA is the recognized national voice for the veterinary profession.

In response to “Veterinary Services Draft Memorandum No. 335: Guidelines for Autogenous Biologics,” the AVMA recognizes the potential resource savings by the Center for Veterinary Biologics with the changes proposed in the draft, especially considering our understanding that extensions for isolate use beyond 15 months has been sought and approved for the majority of autogenous biologics in recent history. Likewise, we understand that nearly all submissions of data to support non-adjacent use of isolates are approved by CVB, saving the Center resources if autogenous manufacturers no longer have to submit data to support such non-adjacent use.

In principle, the AVMA believes that autogenous vaccines should have limited use for specific conditions on specific herds known to have an unusual problem in which commercial products fail or are unavailable. However, veterinarians in today’s production systems evaluate potential usage via animal flow, which may or may not include herds that are geographically located next to each other, making flexibility in this aspect of product utilization critical. Likewise, the ability to use a product for 24 months or more is very valuable when a veterinarian determines that clinical and laboratory assessments demonstrate product effectiveness.

The AVMA acknowledges the on-site utilization of a range of specialists within various animal health programs, including the use of autogenous biologics by

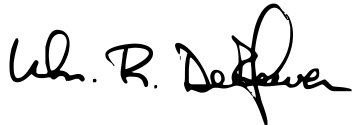
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these specialists. Recognizing that the draft further details qualifications needed for approving non-veterinarian specialists permitted to use the isolates, our recommendation, nonetheless, is that the use of autogenous biologics occur within the oversight of a licensed veterinarian. Similarly, the AVMA supports the draft's requirement for certification of a valid veterinarian-client-patient relationship as defined by AVMA policy.

We appreciate the opportunity to offer our comments on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Ron DeHaven". The signature is fluid and cursive, with a large, stylized initial "W" and "R".

W. Ron DeHaven, DVM, MBA
Executive Vice President
American Veterinary Medical Association