AVMA American Veterinary Medical Association

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June 27, 2005
Docket No. 04-064-1
Regulatory Analysis and Development
PPD APHIS
Station 3C71
4700 River Road, Unit 118
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Docket No. 04-064-1, Proposed Rule: Viruses, Serums, Toxins, and Analogous Products: Expiration Date Required for Serials and Subserials and Determination of Expiration Date of Product

Dear Sir or Madam:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 72,000 members represent approximately 86% of U.S. veterinarians, all of whom are involved in the myriad areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

By proposing to amend 9CFR114.12 and 114.13, the Center for Veterinary Biologics is proposing to change the criterion by which data is generated in support of assigning expiration dates to each licensed serial of vaccine and for determining the expiration dating period (maximum allowable shelf-life) of a product during development and prior to licensure.

It is essential that vaccine products are potent through the dating period. The current regulations should be improved because some interpretations, including those leading to overages of antigenic mass, have allowed for data sets that might not accurately determine the product stability profile. Thus, the AVMA is pleased, in concept, that the CVB is addressing shortcomings in the regulations that could impact product potency, and consequently safety and efficacy.

However, the proposed regulations are written broadly and it is difficult to gauge what additional testing is specifically required. Consequently, it is difficult to determine what assurances will accompany the additional testing and if the proposal is the best approach. We recommend that CVB allow industry and other interested stakeholders input into the process before a final decision is made.

The AVMA supports a science-based stability testing program, one in which statistical methodologies demonstrate a fitness for use for the product and will, with confidence, assure all serials of a product are potent throughout their shelf life.

Thank you for this opportunity to comment.

Respectfully,

Janet D. Donlin, DVM
Assistant Executive Vice President
JDD/ECG