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Department of
Agriculture

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-17

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Subject: Exemption to 3-year Master Seed Immunogenicity Retesting

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

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is currently in the process of reviewing regulations that require Master Seeds of live virus and bacterial vaccines to be retested for immunogenicity 3 years after the initial immunogenicity study.

After review of historical data, we have found that this testing has been uninformative. Therefore, little risk is associated with dropping these requirements and reducing animal testing. Currently, 3-year immunogenicity testing of Master Seeds is required in 9 CFR 113.66(b)(6), 113.67(b)(7), 113.68(b)(6), 113.69(b)(6), 113.70(b)(5), 113.71(b)(4), 113.302(c)(4), 113.303(c)(6), 113.304(c)(4), 113.305(b)(1)(iii), 113.305(b)(2)(iii), 113.306(b)(4), 113.308(b)(5), 113.309(c)(9), 113.310(c)(8), 113.311(c)(7), 113.312(b)(5), 113.313(c)(6), 113.314(c)(4), 113.315(c)(4), 113.316(b)(5), 113.317(c)(4), 113.318(b)(4), 113.325(c)(5), 113.326(c)(5), 113.327(c)(4), 113.328(c)(6), 113.329(c)(5), 113.331(c)(4), and 113.332(c)(4).

The CVB will allow exemptions to these testing requirements until the regulations are revised. Requests for exemptions to these regulations should be addressed to the reviewer assigned to the establishment.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics