



August 3, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-18

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team
Area Veterinarians in Charge
State Veterinarians

FROM: Richard E. Hill, Jr. /s/ Byron E. Rippke, for
Director
Center for Veterinary Biologics

SUBJECT: Novel H1N1 Influenza Master Seed Virus Available from Center for
Veterinary Biologics (CVB)

I. PURPOSE

The purpose of this notice is to inform interested parties that the CVB is accepting requests for novel H1N1 Influenza Master Seed Virus (MSV). The new H1N1 MSVs are derived from several viral isolates, including A/California/04/2009 (H1N1), A/Mexico/4108/2009 (H1N1), and A/reassortant/NYMC X-179A (H1N1).

II. BACKGROUND

CVB Notice 09-10, published June 9, 2009, informed interested parties that the CVB would provide licensed biologics manufacturers with pre-approved MSV for use in the development of a conditionally licensed, multi-dose, monovalent novel H1N1 swine influenza virus (SIV) product for protection of swine in the United States. In the event that the novel H1N1 virus appears to be an emerging disease in swine, the availability of the pre-approved MSV would facilitate a more rapid response should vaccine production be warranted. The novel H1N1 virus has, to date, not been detected in the U.S. domestic swine population, and thus incorporation of the virus into autogenous or existing multivalent products is not authorized.

The MSVs were derived from samples acquired from the Centers for Disease Control and Prevention (CDC) through collaboration between the Agricultural Research Service's National Animal Disease Center and the Animal and Plant Health Inspection Service's CVB.



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III. ACTION

The novel H1N1 MSVs are currently undergoing testing in accordance with Title 9, Code of Federal Regulations. Requests for the new MSV are being accepted in advance of the completion of CVB testing. Firms may obtain samples prior to completion of CVB testing *at their own risk* for purposes of initiating product development activities. Please follow the procedures outlined in Veterinary Services Memorandum 800.97 and CVB Notice 09-10 when requesting samples. Reagent Data Sheets, included with the MSVs, provide instructions for storage and details concerning use.

ARCHIVED