



July 2, 2002

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-13

**United States
Department of
Agriculture**

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
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Subject: Availability of References and Reagents from the
Center for Veterinary Biologics

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

This notice is to inform interested parties of potential delays or shortages of references and reagents from the Center for Veterinary Biologics (CVB). References and reagents are provided as testing aids as described in the Code of Federal Regulations (9 CFR 113.2) to assist U.S. biologics manufacturers to meet codified requirements and as a service to the U.S. biologics manufacturers for agents or procedures without codified requirements. References and reagents are also provided, as a courtesy, to colleges, universities, international scientists, non-U.S. biologics manufacturers, other U.S. and foreign regulatory agencies, and to U.S. allied industries to assist with biological related projects.

The CVB-Laboratory (CVB-L) is presently experiencing a temporary staffing shortage which is affecting the Laboratory's ability to produce and validate references and reagents. Some of the references and reagents normally supplied are either not available or in limited supply.

The CVB asks for your assistance in conserving CVB-L supplied references and reagents. Please limit requests to your immediate requirements and for the reagent's specific use. Where possible, biologic manufacturers should use the CVB supplied reagents as seeds or as a reference material to validate in-house produced reagents. The CVB-L may limit shipment to less than the requested amount when supplies are low in order to assure adequate references and reagents are available to other requestors. The highest priority will be placed on requests from U.S. biologic manufacturer for U.S. use.

The CVB realizes the shortage of certain references and reagents may adversely impact some firms. We apologize for the inconvenience. The CVB remains committed to supplying references and reagents to assist in the regulatory control of U.S. veterinary biologics, especially where the CVB is the sole source of supply. The CVB-L will be prioritizing production of references and reagents based on most critical need and sole source supply. If special situations arise where the quantity of supplied reagents is not adequate to meet an immediate need, please contact the appropriate Section Leader at the CVB-L.

/s/ Steven A. Karli

Steven A. Karli
Director
Center for Veterinary Biologics



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