



December 22, 2005

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-24

Animal and Plant
Health Inspection
Service

Subject: Immediate Notifications to the Center for Veterinary Biologics per 9 CFR Part 116

Veterinary Services

Center for Veterinary
Biologics

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

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

The purpose of this notice is to clarify expectations the Center for Veterinary Biologics (CVB) has in regards to immediate notification under Title 9 Code of Federal Regulations, Parts 116.1(b) and 116.5(b).

Title 9, Code of Federal Regulations, Parts 116.1(b) and 116.5(b) both state, "If, at any time, there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer must immediately notify the Animal and Plant Health Inspection Service concerning the circumstances and the action taken, if any. Notification may be made by mail to Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA, 50010-8197; by electronic mail to cvb@aphis.usda.gov; by fax to (515) 232-7120; or by telephone to (515) 232-5785."

- Immediate notification is required for a released serial of licensed product, or for a serial of licensed product where samples or an APHIS Form 2008 has been submitted
- Compliance with the requirement for "Immediate" notification is considered to be met by notification to CVB within 3 business days.
- Electronic mail notifications must be directed to CVB@aphis.usda.gov and should not be made to a specific individual's electronic mail at the Center. This email is monitored every business day and the notification will be transferred to Inspection and Compliance.

- Telephone notifications may be made directly to CVB Biologics Specialists but they may not be left as recorded messages. In addition, notifications should not be made to other personnel within CVB (i.e. Laboratory or Review Staff). If your Biologics Specialist is not available to take your call, you may dial '0' to get back to the receptionist and they will direct your call to the CVB Inspection and Compliance Program Coordinator that is responsible for taking calls for specialists that are out of the office.
- Notifications sent to CVB by electronic mail, fax, or telephone must be confirmed in writing with an original signature and sent by mail to the CVB.

/s/ Richard E. Hill

Richard E. Hill
Director
Center for Veterinary Biologics

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