# Adverse Event Reporting

Last Modified:

An adverse event is any undesirable occurrence after the use of an immunobiological product, including illness or reaction, whether or not the event was caused by the product. For products intended to diagnose disease, adverse events refer to anything that hinders discovery of the correct diagnosis.

The mission of the Center for Veterinary Biologics (CVB) is to ensure that animal immunobiologics are in compliance with the Virus-Serum-Toxin Act. Reports are assessed for the possibility of a product deficiency. When necessary, testing is performed or additional information sought. The CVB is, however, unable to make diagnoses or recommendations specific to individual cases. Some of the manufacturers do provide such services. Receipt of a report by the CVB does not necessarily imply that the product caused an adverse event, or even that a particular event actually occurred.

The manufacturer is required to report all adverse events they receive to the CVB. Please contact the manufacturer to report adverse events.

**Please note that reporting adverse events to the manufacturer cannot be done from this website. You will need to contact the manufacturer directly.** A contact telephone number may be available on the label of the product or on the manufacturer’s website.

# Reporting Adverse Events for Pharmaceuticals or Insecticides

- Veterinary drugs, medicated feeds, and animal devices are regulated by the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) under the Food, Drug, and Cosmetic Act. The CVM recommends that you first contact the manufacturer to report an adverse event. To contact the CVM directly, call 888-FDA-VETS.
- Topical insecticides—Most of the products used topically for the control of ectoparasites and insects on animals are regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide Fungicide and Rodenticide Act. To contact the EPA directly, call 800-858-7378.

**If unable to report an adverse event to the manufacturer of an animal immunobiologic product regulated by the CVB, you may contact us using one of the methods below.**

- Online (*preferred method*): USDA Adverse Event Reporting—use form "Public Adverse Event Report"
    - Instructional Guidance for PV Express II for Public Submissions (745.04 KB)
- Fax or Mail: Download and complete the Adverse Event Report Form (APHIS 2080) (258.76 KB) and fax to 515-337-6120 or submit to us by mail at Center for Veterinary Biologics, 1920 Dayton Ave., P.O. Box 844, Ames, IA 50010.
- Phone: Call the CVB at 800-752-6255.

# More Information

See frequently asked questions on adverse event reporting/pharmacovigilance.

**Are you a manufacturer looking for guidance?** Go to Adverse Events Industry Guidance for Compliance to 9 CFR 116.9.

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