Adverse Events Industry Guidance

Last Modified:

The Virus-Serum-Toxin Act regulations concerning records and reports, as specified in 9 CFR 116.9, require veterinary biologics licensees and permittees to record and submit reports concerning adverse events associated with the use of the veterinary biological products they produce and distribute.

These records and reports will assist VS in monitoring the performance of licensed veterinary biological products over time, while also allowing VS to provide complete and accurate information to consumers regarding adverse events or other possible concerns associated with the use of these products.

General Instructions

View a complete guide to reporting adverse events to the CVB using PV Express II (1.09 MB)

Click the button to go directly to the manufacturer's site to submit adverse events (per 9 CFR 116.9):

USDA Adverse Event Reporting

Supporting Documents

Veterinary Services Memorandum 800.125

(PDF, 293.05 KB)

Preparation and Submission of Adverse Event Reports for Biological Products by Licensees and Permittees

Guidance Notes on the Use of VeDDRA Terminology

(for licensed firms)

Complete VeDDRA List

(for licensed firms)

Doses Distributed Reporting Template

(Excel, 10.58 KB)

(Firms with no AERs to report must submit a letter indicating no AERs were received.)

Contact Us

For technical support, please email us at CVB.Pharma@usda.gov

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