

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Procedure

Guidelines for the Pharmacovigilance Monitoring Committee

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Guidelines for the Pharmacovigilance Monitoring Committee

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Guidelines for the Pharmacovigilance Monitoring Committee

1. Purpose

This Standard Operating Procedure (SOP) outlines the procedures and function of the Center for Veterinary Biologics (CVB) Pharmacovigilance Monitoring Committee.

2. Definitions

2.1 Pharmacovigilance Monitoring Committee (PMC): A group of individuals that reviews information gathered from adverse event reports and other pharmacovigilance activities. Collectively the committee has the education, experience, and expertise necessary to make recommendations regarding appropriate regulatory actions to be taken to safeguard animal and public health.

2.2 PMC Chairperson: The Biologic Epidemiologist will serve as the Chairperson.

3. Responsibilities

3.1 The PMC Chairperson shall:

- Compile references, data, and appropriate background material for PMC;
- Announce meetings;
- Prepare agenda and lead meetings;
- Write and post minutes of meetings and decisions on the shared drive; and
- Summarize results and present these to the Section Leaders and CVB Management Teams.

3.2 The PMC Members shall:

- Research pertinent information prior to meetings;
- Identify issues and concerns;
- Propose options (solutions);
- Analyze expected consequences of various actions; and
- Recommend a course of action to be taken by CVB-Inspection and Compliance (IC) and/or CVB-Policy, Evaluation, and Licensing (PEL) depending on the nature of the action.

4. Establishment of the PMC

Other than the Chairperson, the CVB Directors will appoint standing members of the PMC. The lengths of the appointments are at the discretion of the Directors. The members shall include:

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- PMC Chairperson
- At least one standing member from PEL Senior Staff
- At least one standing member will be from the Biometrics Section
- Alternate members as needed based on the issues to be discussed

5. Expected Product

The expected product from the PMC is a recommended action. A discussion of critical issues should be included in the document. For controversial issues, pro and con statements will be prepared by team members and provided to the Compliance Section Leader with a draft for review and decision with CVB Management Teams.

6. PMC Documentation

Minutes are posted on the shared drive FOIA Exemption #2 [REDACTED]
[REDACTED]
within one week of the meeting. A listing of participating PMC members is to be included with each set of minutes.