

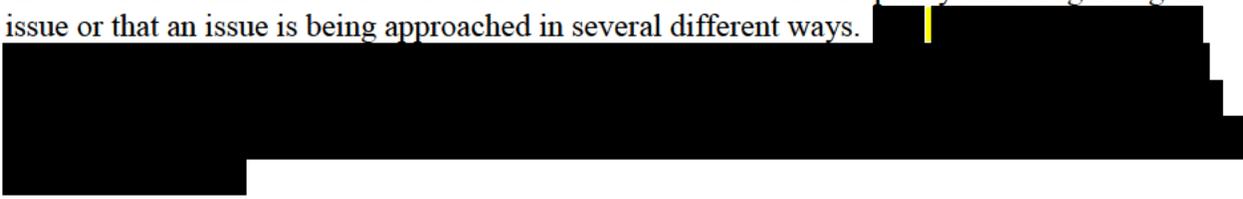
1.4 Reviewer Staff Meeting

Introduction

Center for Veterinary Biologics Policy Evaluation and Licensing (CVB-PEL) Reviewer Staff meetings provide an opportunity for staff to discuss current issues regarding licensure of new and existing products, as well as provide a forum for communicating information of common interest. Regular attendees of PEL staff meetings include the PEL Reviewers, Statisticians, Section Leaders, CVB PEL Director, and recorder (Program Support Assistant to the PEL Director). A standing invitation has also been issued to the Legal Instrument Examiners, Program Assistants, and the CVB Assistant Director. Other attendees may also be invited to these meetings, based on the agenda.

Types of Issues Discussed at Staff Meetings

Issues discussed at staff meetings include consistency questions, regulatory issues, and informational items. *Regulatory* issues are items that require generation of new policy, or confirmation of existing policy. *Informational* items are presented to inform other reviewers of current events, and may include such things as Coordinated Review Team reports, training summaries, or reviews of scientific educational materials. *Consistency Questions* are posed regularly as a means to determine how reviewers currently handle a particular issue. They may arise from review of historical files, the Reviewers' Manual, published Notices and Memos, and/or when communication with other Reviewers indicates that no policy exists regarding an issue or that an issue is being approached in several different ways.



Procedure for Adding a Topic to the Agenda:

Regulatory items that require an immediate decision to facilitate review should be discussed with the appropriate Section Leader prior to the staff meeting (e.g., issues related to bacterins should be discussed with the Bacteriology Section Leader). The Section Leader will either resolve the issue through such discussion (i.e. provide guidance regarding the appropriate action to take) or approve the issue to be brought to the staff meeting for discussion.

If the item is approved for discussion at the staff meeting, the originator should email a summary of the issue to the Program Support Assistant to the PEL Director no later than close of business the Monday prior to the meeting. The Assistant will add the item to the agenda, and will email an agenda to all attendees prior to the meeting.

Informational items should be emailed to the Program Support Assistant to the PEL Director for inclusion on the agenda. Informational items also may be discussed at the staff meeting without prior notice.

Consistency Questions are submitted to the Consistency Question Coordinator. The item may be submitted as a detailed description of the issue or an actual consistency question (i.e., scenario with several possible answers). The Consistency Question Coordinator will edit as necessary for grammar and clarity, then confirm the question phrasing with the originator. The question is then emailed to all Reviewers for a response prior to the meeting, as well as to the Program Support Assistant to the PEL Director for inclusion on the next staff meeting agenda. The Consistency Question Coordinator compiles the Reviewers' responses, and presents a summary at the next staff meeting.

Documentation of Staff Meeting Discussion

Staff meeting notes are posted

