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GENERAL PROCEDURAL POLICIES

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EVALUATION OF PROPOSED LEGISLATION

Legislation proposed or enacted that directly or indirectly impacts on the programs of the Center for Veterinary Medicine requires review and evaluation. Such legislation may be initiated by the agency or by Congress. The Center may also be called upon to review and comment on legislation proposed for enactment by the states.

1. **Purpose:**

This program has been developed to insure that proposed legislation forwarded to the attention of the Center is evaluated for impact on FDA/CVM policies, procedures, regulations, and program responsibilities.

2. **Objectives of Evaluation:**

Evaluation of bills proposed in state legislatures or in Congress will be coordinated by the Policy and Regulations Team, HFV-6 in order to:

- a. Offer comment on legislation which may impact on the Center's responsibilities;
- b. Be aware of legislation which may be of general interest to CVM even though it may not directly affect the Center; and
- c. Be aware of any general trends which are developing.

3. **Evaluation of Procedures:**

- a. All proposed legislation will be initially summarized and evaluated by the Policy and Regulations Team. They will log all legislation received, recording the date received, source, subject, and disposition. Evaluations shall be made within the requested time frames.
- b. The Team Leader, Policy and Regulations Team evaluates the comments/ recommendations of the Staff; forwards copies of the bills and the evaluation to

the appropriate CVM offices for additional review/ action as needed; or files the materials for a period of one year for future reference.

- c. Center offices receiving copies shall evaluate the proposed legislation within established time frames. Comments will be routed to HFV-6 and forwarded through the Division of Compliance, HFV-230 for concurrence.
- d. Division of Compliance shall forward all comments to the CVM Director's office, HFV-1 through the Director, Office of Surveillance and Compliance for action as required. Copies of all final comments and disposition of the documents shall be forwarded to HFV-6 for logging and filing purposes.
- e. The Director, Office of Management and Communications, will review and evaluate all proposed legislation and comments for budget implications and economic impact to ensure that CVM's responses are thoroughly researched and coordinated. Comments, corrections, and recommendations by the Director, Office of Management and Communications, will be forwarded to the Policy and Regulations Team, HFV-6 for consolidation of Center comments.
- f. Usually on an annual basis, an opportunity is given for the Center to initiate proposed amendments to the Act to improve the Agency's effectiveness. Such proposals are coordinated and reviewed by the Office of Legislative Affairs, HFW-1. Following concurrence by a review team and the Commissioner the proposal is forwarded to the Department.