Form: TH- 05 3/31/00



Periodic Review and Retention of Existing Regulations Agency Background Document

Agency Name:	Department of Agriculture and Consumer Services
VAC Chapter Number:	2 VAC 5-370
Regulation Title:	Rules and Regulations for the Enforcement of the Virginia Animal Remedies Law
Action Title:	Retain
Date:	September 5, 2001

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to retain an existing regulation.

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

This regulation establishes (1) standards for manufacturers of animal remedies related to proper equipment and qualifications of personnel involved in the production of animal remedies; (2) criteria for storage of biological products used in production, and (3) specifies the methods of sampling and analysis of animal remedies.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or

discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

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This regulation is authorized by §3.1-839 of the Code of Virginia (1950), as amended. While the wording of this section appears to be discretionary, the section does authorize the Board of Agriculture and Consumer Services to promulgate such regulations as necessary to carry out the provisions Chapter 29, Animal Remedies Law. The regulation is necessary for the purpose of establishing the sampling and analysis criteria to carryout the enforcement of Chapter 29. Without the regulation, there would be no basis for any enforcement actions related to truth-in-labeling.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

The agency received no public comment on this regulation as the result of the Notice of Periodic Review published in *The Virginia Register of Regulations* on June 18, 2001, to provide notice of opportunity to comment on this regulation pursuant to Executive Order Number Twenty-five (98). No informal advisory group was formed for the purposes of assisting in the periodic review.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. Please assess the regulation's impact on the institution of the family and family stability. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The specific and measurable goals of this regulation are:

- (1) The protection of the public's health, safety, and welfare with the least possible cost and intrusiveness to the citizens and businesses of the Commonwealth, and
- (2) Ensuring that over-the-counter animal medications are truthfully labeled.

This regulation is effective since it serves to clarify provisions within the Code of Virginia and provides guidance to individuals affected. The regulation also serves to prevent unscrupulous manufacturers from intentionally marketing products that will cause harm to Virginia agriculture and consumers.

This regulation is clearly written and easily understood by individuals and entities affected.

Alternatives

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Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The agency has considered and rejected repealing this regulation. In the absence of the regulation, Virginia citizens would not be protected from the possible introduction of adulterated food due to the contamination by unregulated animal remedies. Additionally, substandard animal remedies would be unregulated. These substandard animal remedies would not provide the expected level of protection to the animal and could lead to unnecessary suffering for the animal and economic losses for the animal producer.

Recommendation

Please state that the agency is recommending that the regulation should stay in effect without change.

The agency recommends that this regulation be retained in its present form.

Family Impact Statement

Please provide an analysis of the regulation's impact on the institution of the family and family stability including the extent to which it: 1) strengthens or erodes the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourages or discourages economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthens or erodes the marital commitment; and 4) increases or decreases disposable family income.

Unless otherwise discussed in this report, this regulation has no impact upon families.