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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 01-067-2]

Viruses, Serums, Toxins, and Analogous Products; Determination of Moisture Content in Desiccated Biological Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Virus-Serum-Toxin Act regulations for the determination of moisture content in desiccated biological products to require that such determinations be made using a gravimetric method that expresses moisture content as the percentage of weight a product loses during a drying cycle, and to require that the maximum percentage of moisture permitted for a satisfactory test must be specified in a filed Outline of Production. The gravimetric method has been adopted as an international standard by scientific experts and regulatory authorities in the United States, Canada, Japan, and the European Union. In addition, we are amending the regulations pertaining to general requirements for live bacterial vaccines and general requirements for live virus vaccines to specify the gravimetric method when testing for moisture content. These actions will update the regulations by providing a uniform method of determining moisture content in desiccated products and ensure the stability of that product during its dating period.

EFFECTIVE DATE: November 5, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Licensing and Policy Development, Center for Veterinary Biologics, VS, APHIS, 4700 River Road

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SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 113 (referred to below as the regulations) prescribe standard requirements for the preparation and testing of veterinary biological products. Standard requirements consist of test methods, procedures, and criteria that define the standards for purity, safety, potency, and efficacy for a given type of veterinary biologic product. When a standard procedure for testing veterinary biological products is validated and approved by the Animal and Plant Health Inspection Service (APHIS) for general use, it is proposed for codification in the regulations. Section 113.29 of the regulations sets forth the requirement for determination of moisture content in desiccated biological products.

On August 5, 2002, we published in the **Federal Register** (67 FR 50606-50608, Docket No. 01-067-1) a proposal to amend the regulations for determination of moisture content in desiccated biological products to specify that such determinations be made using a gravimetric method, and to require that the maximum percentage of moisture permitted for a satisfactory test must be specified in a filed Outline of Production. The proposed rule was intended to update the regulations by providing a uniform method of determining moisture content in desiccated products and ensure the stability of that product during its dating period.

We solicited comments on our proposed rule for 60 days ending on October 4, 2002. We received two comments by that date, from a veterinary biologics manufacturer and a national trade association representing veterinary biologics manufacturers. Both commenters supported the proposed rule. One commenter did, however, request that we "clarify the exceptions to the use of the proposed method." The commenter recommended that if we intend to handle such instances via outline exemptions, then that should be stated. Additionally, the commenter asked that we indicate whether one valid reason for an exemption would be

that a firm does not have the equipment necessary to conduct the test.

In this final rule, we are adopting the gravimetric method as the standard procedure for determining moisture content. As a Standard Requirement test, the gravimetric method should be used whenever the test for moisture content is performed. However, we note that exemptions to the use of the gravimetric method, like exemptions to any test prescribed in the various standard requirements found in part 113, may be granted for any valid reason in accordance with § 113.4, "Exemptions to tests." Exemption requests are evaluated on a product-by-product basis, and in our review of such requests, we focus on the methods, equipment, and procedures that would be used in place of those prescribed in the Standard Requirement. It is the validity of the alternative methods and procedures that serves as the basis for the granting of an exemption.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are amending the Virus-Serum-Toxin Act regulations for determination of moisture content in desiccated biological products to require that such moisture determinations be made using a gravimetric method that determines residual moisture by measuring the percentage of weight a product loses during a product drying cycle. In addition, this rule provides that the maximum percentage of moisture permitted for a satisfactory test must be specified in a filed Outline of Production. The effect of this action will be to provide a standardized method for the determination of moisture content in desiccated biological products that has been adopted internationally and ensure that such moisture determinations are uniform and reproducible.

This rule will affect all licensed manufacturers of veterinary biologics that test desiccated vaccines for moisture content. Currently, there are approximately 135 veterinary biologics