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VS Memorandum (VSM) 800.106

Exemption to Sterility Test Requirement for Allergenic Extract Prescription Product

1. Purpose and Background

This memorandum provides guidance for obtaining an exemption to the requirement for sterility testing of Allergenic Extract, Prescription Product, Product Code 9531.00. Regulations in title 9, *Code of Federal Regulations* (9 CFR), 114.9(e)(III) require Outlines of Production for allergenic extracts to include testing methods for purity, safety, potency, and other pertinent tests. Purity, or sterility, testing must be conducted in a manner consistent with 9 CFR 113.25 and 113.26. However, the current regulations do not provide specific guidance for sterility testing of Allergenic Extract, Prescription Product.

An Allergenic Extract, Prescription Product, consists of one or more vials of individual or mixed allergenic extracts, undiluted or prepared as a dilution series, compounded in accordance with a prescription ordered by a licensed veterinarian engaged in a valid veterinarian-client-patient relationship. The written prescription must identify an individual client and patient. The filled prescription product is used for the diagnosis or treatment of allergies of an individual animal. The licensed veterinarian administers, or oversees the administration of, the prescription product.

This memorandum clarifies CVB policy regarding testing of Allergenic Extract, Prescription Product, by granting an exemption from 9 CFR 113.25 and 113.26 sterility testing. However, 9 CFR 114.9(e)(III) tests remain a requirement for individual or mixed allergenic extracts prior to formulation as Allergenic Extract, Prescription Product.

2. Document Status

A. Issue Date: 02/11/2022

B. This document replaces Veterinary Services Memorandum 800.106, dated December 9, 2002, which is cancelled.

3. Reason for Reissuance

CVB is updating this document to clarify CVB policy regarding testing of Allergenic Extract, Prescription Product, Product Code 9531.00.

4. Authority and References

Authorities

- Virus Serum Toxin Act (21 U.S.C. 151-159)
- 9 CFR 114.9
- 9 CFR 113.25

- 9 CFR 113.26

5. Audience

VS employees and members of the biologics industry.

6. Guidance

A. Policy

The 9 CFR 113.25 and 113.26 sterility testing of finished Allergenic Extract, Prescription Product, is not required provided the following requirements are met:

1. Sterile Ingredients

All ingredients must be sterile prior to compounding of the prescription product.

Where both allergenic extract and Allergenic Extract, Prescription Product, are produced in a USDA-licensed establishment, satisfactory test results on the allergenic extract(s) used to prepare Allergenic Extract, Prescription Product, must be maintained within the establishment.

Where only Allergenic Extract, Prescription Product is produced in a USDA-licensed establishment, a certificate of analysis from the USDA-licensed establishment that produces and supplies constituent allergenic extract(s) may substitute for testing by the manufacturer of the prescription product. Include the test results listed in Section V of the supplying manufacturer's filed Outline of Production in the certificate of analysis. Only extract and diluent serials with certified satisfactory test results demonstrating fulfillment of 9 CFR 113.25 and 113.26 requirements are acceptable for use in compounding Allergenic Extract, Prescription Product.

2. Sterility Test Records Available for Review

Maintain and make available test results and/or certificate(s) of analysis for review at the time of inspection by CVB-Inspection and Compliance, or upon CVB request.

3. Adequate Preservative

The composition of the prescription product includes preservative at such concentration necessary to maintain bacteriostatic and fungistatic activity (e.g., phenol concentration of 0.4 percent).

4. Exemption Noted in the Outline of Production

   Indicate the date the exemption to the purity test specified under 9 CFR 113.26 was granted in Section III.A. of the Outline of Production. Include the CVB mail log number of the letter granting the exemption if known.

7. Implementation/Applicability

   Updated policy in this memorandum is effective immediately.