

policies and procedures of the Department. At the conclusion of an investigation of an allegation or complaint of violation of § 287.8, the investigative report shall be referred promptly for appropriate action in accordance with the policies and procedures of the Department.

(d) *Unsubstantiated complaints.*

When an investigative report does not support the allegation, the employee or officer against whom the allegation was made shall be informed in writing that the matter has been closed as soon as practicable. No reference to the allegation shall be filed in the official's or employee's official personnel file.

(e) *Jurisdiction of Department of Justice organizations.* Nothing in this section alters or limits, is intended to alter or limit, or shall be construed to alter or limit, the jurisdiction or authority conferred upon the Federal Bureau of Investigation, the United States Attorneys, the Criminal Division or the Civil Rights Division, or any other component of the Department of Justice that may have jurisdiction regarding criminal violations of law.

■ 20. Section 287.12 is revised to read as follows:

§ 287.12 Scope.

With regard to this part, these regulations provide internal guidance on specific areas of law enforcement authority. These regulations do not, are not intended to, and shall not be construed to exclude, supplant, or limit otherwise lawful activities of the Department or the Secretary. These regulations do not, are not intended to, shall not be construed to, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter, civil or criminal. The Secretary shall have exclusive authority to enforce these regulations through such administrative and other means as he may deem appropriate.

Dated: June 6, 2003.

Tom Ridge,

Secretary of Homeland Security.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 01-091-2]

Viruses, Serums, Toxins, and Analogous Products; Standard Requirements for Determination of Residual Free Formaldehyde Content of 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 residual free formaldehyde in veterinary biologics to specify that such determinations be made using the ferric chloride method, and that the residual free formaldehyde content be measured in grams per liter. The ferric chloride method has been adopted as an international standard by scientific experts and regulatory authorities in the United States, Canada, Japan, and the European Union. The effect of this rule will be to reduce the differences in technical requirements for veterinary biologics among regulatory agencies in different countries and further ensure the safety and shelf life of veterinary biologics by adopting a method that has been standardized and accepted internationally.

EFFECTIVE DATE: July 14, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD, 20737-1231; (301) 734-8245.

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 biological 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. Sections 113.100 and 113.200 of the

regulations prescribe the requirement for determination of residual free formaldehyde content in inactivated bacterial products and killed virus vaccines, respectively.

On April 5, 2002, we published in the **Federal Register** (67 FR 16327-16329, Docket No. 01-091-1) a proposal to amend to amend the regulations for determination of residual free formaldehyde content in inactivated bacterial products and killed virus vaccines to specify that such determinations be made using the ferric chloride method, and that the residual free formaldehyde content be measured in grams per liter. The proposed rule was intended to reduce the differences in technical requirements for veterinary biologics among regulatory agencies in different countries and further ensure the safety and shelf life of veterinary biologics by adopting a method which has been standardized and accepted internationally.

We solicited comments concerning our proposal for 60 days ending on June 4, 2002. We received one comment by that date, from a national trade association representing veterinary biologics manufacturers. The commenter expressed support for the efforts of APHIS and the International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) to harmonize the technical requirements for product registration among the participating regions and recommended that APHIS adopt the provisions of the proposed rule.

Therefore, for the reasons given in the proposed rule, 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 residual free formaldehyde content in biological products to require that such free formaldehyde determinations be made using the ferric chloride method, which determines residual free formaldehyde content by measuring the quantity of coloring matter in solution by the quantity of light absorbed in passing through the solution. In addition, this rule provides that the maximum allowable residual free formaldehyde content of veterinary