

could be produced at the same time under both a Federal and State license.

We solicited comments concerning our proposal for 60 days ending May 5, 1995. We did not receive any comments. The proposed rule provides the basis for this final rule.

Therefore, based on the rationale set forth in the proposed rule, we are adopting the provisions of the proposal 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 purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

This rule removes outdated sections from the regulations in §§ 102.1 and 102.4(h) and § 114.2 (b) and (d). These sections refer to outdated provisions related to the implementation of the 1985 amendments to the Virus-Serum-Toxin Act. These provisions expired on June 30, 1991.

This rule also establishes conditions applicable to some 100 producers to prepare a biological product under either a State or USDA product license in a USDA licensed establishment. An exception is provided for autogenous biologics. The amendment will not have an adverse economic impact on these producers of biologics since it still allows the production of both State and Federally licensed products in Federally-licensed establishments. Therefore, it is not anticipated that the amendment will have an economic impact on producers or small businesses.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative

procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This document contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects

9 CFR Part 102

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 114

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 102 and 114 are amended as follows:

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

1. The authority citation for part 102 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 102.1 is revised to read as follows:

§ 102.1 Licenses issued by the Administrator.

Each establishment qualified to prepare biological products under the Virus-Serum-Toxin Act shall hold an unexpired and unrevoked U.S. Veterinary Biologics Establishment License issued by the Administrator and a U.S. Veterinary Biological Product License for each product prepared in such establishment unless the product is subject to the provisions of 9 CFR parts 103 or 106 of this subchapter.

§ 102.4 [Amended]

3. In § 102.4, paragraph (b)(3), the words "Veterinary Services" are removed and the words "Animal and Plant Health Inspection Service" are added in their place.

4. In § 102.4, paragraph (h) is removed.

§ 102.6 [Amended]

5. In § 102.6, in the introductory paragraph and paragraph (a), the term "Deputy" is removed.

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

6. The authority citation for part 114 is revised to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

7. In § 114.2, paragraphs (b) and (d) are removed; paragraph (c) is

redesignated as paragraph (b) and revised; and a new paragraph (c) is added to read as follows:

§ 114.2 Products not prepared under license.

* * * * *

(b) Except as provided in 9 CFR part 103, a biological product shall not be prepared in a licensed establishment unless the person to whom the establishment license is issued holds an unexpired, unsuspended, and unrevoked product license issued by the Administrator to prepare such biological product, or unless the products prepared are subject to the provisions of § 107.2 of this subchapter.

(c) A biological product produced in a USDA-licensed establishment shall be produced under a U.S. Veterinary Biological Product License or a license granted by a State under § 107.2 (referred to as a State biological product license and the products prepared pursuant thereto as State-licensed biological products, including autogenous biologics), but not under both a U.S. Veterinary Biological Product License and a State biological product license. Before a U.S. Veterinary Biological Product License (including a conditional license) is issued, the licensee shall relinquish its State license for that product: *Provided*, That autogenous biologics shall not be subject to this provision when they are prepared in accordance with the provisions of paragraph (c)(5) of this section.

(1) State-licensed biological products (including autogenous biologics) shall only be distributed or shipped intrastate, must not bear a U.S. Veterinary Biologics Establishment License Number, and must not otherwise be represented in any manner as having met the requirements for a U.S. Veterinary Biological Product license. Labeling of State- and USDA-licensed biological products produced in the same establishment must be distinctly different in color and design.

(2) All biological products in USDA-licensed establishments, whether licensed by USDA or by the State, shall be prepared only in locations indicated in legends filed in accordance with 9 CFR part 108. A description of each State-licensed product must be filed with the Animal and Plant Health Inspection Service as part of the blueprint legends and must be sufficient for Animal and Plant Health Inspection Service to determine any risk to the production of other products in the licensed establishment and to determine that adequate procedures are followed