Executive Order 12866 and Regulatory **Flexibility Act**

This proposed 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.

The proposed rule would amend the regulations in 9 CFR parts 102, 104, 105, and 116 to clarify existing provisions concerning licenses, inspections, records, and reports. Licenses are issued on condition that the licensee permit inspection of establishments, products, and records. The proposed rule would provide that the failure to permit such inspection would make the license subject to suspension or revocation. In order to hold a valid establishment license, licenses are required to have at least one unexpired, unsuspended, and unrevoked product license. Otherwise, the establishment license would be invalid. We are also proposing amendments concerning the content of records and reports and the availability of their inspection.

The proposed rule would make clear and unambiguous certain regulatory provisions. No new requirements are added in the proposed rule. Therefore, no adverse economic impact would result from the rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would 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 proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been approved

by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579-0013.

List of Subjects

9 CFR Part 102

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 104

Animal biologics, Imports, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 105

Animal biologics.

9 CFR Part 116

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 102, 104, 105, and 116 would be revised as follows:

PART 102—LICENSES FOR **BIOLOGICAL PRODUCTS**

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

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

2. In §102.2, the introductory paragraph would be designated as paragraph (a) and a new paragraph (b) would be added to read as follows:

*

§102.2 Licenses required. *

(b) An applicant who applies for an establishment license must also apply for at least one product license. An establishment license will not be issued without a license authorizing the production of a biological product in the establishment.

3. In §102.4, paragraph (f) would be revised, paragraphs (g) and (h) would be redesignated as paragraphs (h) and (i), respectively, and new paragraph (g) would be added to read as follows:

§102.4 U.S. Veterinary Biologics Establishment License.

*

(f) When a licensee no longer holds at least one unexpired, unsuspended, or unrevoked product license authorizing the preparation of a biological product, or is in the process of obtaining a product license, the establishment license shall no longer be valid and shall be returned to the Administrator. In the case where an establishment license expires or is suspended or revoked, any product license authorizing preparation of a product at such establishment shall be invalid

indefinitely or for as long as the suspension is in effect.

(g) Any license issued under this Part to establishments in which biological products are prepared shall be issued on condition that the licensee permit the inspection of such establishments, products, product preparation, and all relevant records as provided in Part 115. Failure to permit inspection may result in the license being suspended or revoked.

PART 104—PERMITS FOR **BIOLOGICAL PRODUCTS**

4. The authority citation for part 104 would continue to read as follows:

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

§104.6 [Amended]

5. In §104.6, paragraph (b), the words "Veterinary Services" would be removed and the words "Animal and Plant Health Inspection Service" would be added in their place.

6. In 9 CFR part 105, the heading for the part would be revised to read as follows:

PART 105—SUSPENSION, **REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS**

7. The authority citation for part 105 would continue to read as follows:

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

8. In §105.1, paragraphs (a)(4) and (a)(5) would be redesignated paragraphs (a)(5) and (a)(6), new paragraph (a)(4)would be added, and redesignated paragraph (a)(5) would be revised to read as follows:

§105.1 Suspension or revocation. *

- * *
- (a) * * *

(4) The licensee, permittee, or the foreign manufacturer has failed to maintain and make available for inspection records in connection with the development and preparation of product, has failed to provide complete and accurate information when requested, or has failed to provide complete and accurate information in the Outline of Production or in reports and records:

(5) The licensee or permittee has violated or failed to comply with any provision of the Virus-Serum-Toxin Act or the regulations in this subchapter;

9. Section 105.4 would be revised to read as follows: