

under either a State or Federal product license. No autogenous biologic could be produced at the same time under both a Federal and State license. The amendment is necessary in order to ensure the integrity of the Federal licensing system and the safety of biological products produced in Federally licensed establishments.

We are also removing outdated sections from the regulations referring to interim establishment licenses and exemption procedures that were permitted during the 5-year transition period to attain Federal licensure under the 1985 amendments to the Virus-Serum-Toxin Act.

**DATES:** Consideration will be given only to comments received on or before May 5, 1995.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 93-136-1, Animal and Plant Health Inspection Service, Regulatory Analysis and Development, Program and Policy Development, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 93-136-1.

Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requests to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20723-1237, (301) 734-8245.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, licenses veterinary biological products under the Virus-Serum-Toxin Act (21 U.S.C. 151-159, hereinafter, the Act), as amended by the Food Security Act of 1985. Veterinary biologics licensed by APHIS include products such as vaccines, antitoxins, viruses, diagnostics, and autogenous biologics (vaccines, bacterins, and toxoids) which are normally used in the herd of origin (the herd from which the disease causing microorganism is derived) to immunize animals against infectious disease.

Under the Act, veterinary biological products are licensed on the basis of their purity, safety, potency, and efficacy. The 1985 amendments to the Act exempt certain products from the

requirement that they be produced pursuant to an unsuspended and unrevoked Federal license. Such products include those which are prepared solely for distribution within the State of production pursuant to a license granted by such State under a program approved by the Administrator of APHIS.

The regulations in 9 CFR part 102 contain Federal licensing provisions for biological products. This proposed rule would amend the regulations in part 102 by removing the outdated reference to Federal interim licenses in § 102.1 and by removing § 102.4(h), which refers to outdated provisions. We would also be making minor editorial changes to § 102.4(b)(3) and § 102.6 (introductory paragraph and paragraph (a)) to reflect organizational changes within APHIS.

The regulations in 9 CFR part 114 prescribe conditions under which an unlicensed product may be prepared in a USDA-licensed establishment. Section 114.2(c) prohibits the production of unlicensed veterinary biological products in licensed establishments, except when an establishment is licensed by USDA for an interim period as provided in § 114.2(b), when production of an experimental biological product is authorized in accordance with 9 CFR part 103, or when biological products are subject to the provisions of § 107.2 (products produced under State license).

The proposed rule would amend part 114 by removing from § 114.2 paragraphs (b) and (d) which refer to outdated provisions for interim licenses and to certain exemption procedures that were used in implementing the 5-year transition to Federal licensure under the 1985 amendments to the Virus-Serum-Toxin Act.

The proposed rule would also establish the conditions that must be maintained when a State-licensed veterinary biological product is produced in an establishment holding a U.S. Veterinary Biologics Establishment License. The proposed rule would require that an establishment holding a U.S. Veterinary Biologics Establishment License that is also producing products licensed by a State may produce a product either under a U.S. Veterinary Biological Product License or a State product license, but the establishment cannot produce the same product under both USDA and State product licenses. It should be noted that in order to be Federally licensed, an establishment must hold at least one Federal product license. Autogenous biologics would not be subject to the proposed requirement in that an establishment may hold both

a State and Federal product license for autogenous biologics but each serial of an autogenous biologic must either be produced pursuant to the State license or the Federal license. The wide variety of different autogenous biologics that are made and the different conditions for their use dictate the need for choosing to produce some of these products under a State product license and others under a USDA product license. This choice would permit such establishments to produce autogenous biologics for intrastate use only, under a State product license, or for both intrastate or interstate use, under a U.S. Veterinary Biological Product License, provided that certain conditions of production are maintained. This proposed rule would define such conditions and ensure that the primary regulatory responsibility for each serial of product is clearly identified prior to production.

Under the proposed amendments, a biological product produced in a USDA-licensed establishment could be produced under either a State or U.S. Veterinary Biological Product License, but not both. Prior to the issuance of a U.S. Veterinary Biological Product License (including a conditional license), any State product license for the same product would have to be surrendered to the State licensing authority. As explained previously, autogenous biologics would not be subject to these requirements.

Under the proposed amendments, State-licensed products (including autogenous biologics) would only be allowed to be distributed or shipped intrastate, would not be allowed to bear a U.S. Veterinary Biological Product License Number, or otherwise be represented as having met the requirements for USDA product licensure. Labeling of State- and USDA-licensed products produced in the same establishment would be required to be distinctly different in color and design.

All biological products in USDA-licensed establishments, whether State- or USDA-licensed, would only be prepared in locations indicated in legends filed in accordance with 9 CFR part 108. A description of each State-licensed product would have to be filed with APHIS as part of the blueprint legends that is sufficient for APHIS to determine any risk to other products in the establishment and to ensure that contamination does not occur during production.

The proposed amendments would also specify that certain reporting and recordkeeping requirements have to be met for both State- and USDA-licensed products.