USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 23-07

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Dr. David White
Acting Director

DAVID WHITE Digitally signed by DAVID WHITE
Date: 2023.03.24 12:38:06 -05'00'

SUBJECT: Sale of Unlicensed Autologous Therapeutic Biologics

I. PURPOSE

This Notice informs applicants that all unlicensed autologous therapeutic biologics, regulated under Veterinary Services Memorandum (VSM) 800.121 *Autologous Therapeutic Biologics*, will no longer be allowed for sale as experimental biologic products as of June 30, 2025.

II. BACKGROUND

On June 21, 2017, the Center for Veterinary Biologics (CVB) published VSM 800.121, which provided a licensure pathway for autologous therapeutic biologics. Prior to VSM 800.121, CVB viewed autologous therapeutics as manufacturing processes, not as licensable products. VSM 800.121 stated that applicants should generate sufficient data for licensure within 2 years and extensions beyond 2 years to sell the unlicensed experimental product may be allowed by CVB. This 2-year grace period allowed time for applicants to come into compliance with CVB guidance by allowing the sale of unlicensed products during the prelicense process. CVB has provided flexibility and extensions as applicants have generated data for licensure; however, the flexibility allowing prelicense sales cannot be for an indefinite period. After June 30, 2025, all autologous therapeutic biologics will be treated like conventional prelicense products and must obtain licensure prior to sale.

Applicants currently selling unlicensed autologous therapeutic biologics have been previously informed that June 30, 2023, would be the final date for selling unlicensed product. The extended June 30, 2025, deadline provides additional time to these applicants. The June 30, 2025, deadline provides a total of 8 years to both generate data for licensure and sell unlicensed product since the 2017 publication of VSM 800.121. Any new applicants that make an application to CVB prior to June 30, 2023, will still be allowed 2 years of prelicense sales as is currently stated in VSM 800.121.

III. ACTION

All applicants developing products intended for an Autologous Prescription Product license should make a formal request to CVB for authorization for shipment and sale of their unlicensed autologous therapeutic biologics as experimental biologic products by June 30, 2023. The request should document progress made toward licensure and request that shipment and sales of unlicensed product be allowed until June 30, 2025. Approval of these requests will be contingent upon CVB receipt of all necessary information documenting progression toward licensure and compliance with VSM 800.121. Products that fail to meet these conditions will only be allowed for sale after licensure.

VSM 800.121 will be revised to reflect this change.

IV. IMPLEMENTATION/ APPLICABILITY

This policy is effective immediately.