



Animal and Plant  
Health Inspection  
Service

Veterinary Services  
Center for Veterinary  
Biologics

1920 Dayton Avenue  
PO Box 844  
Ames, IA 50010

(515) 337-6100

## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 22-03

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

**FROM:** Byron Rippke  
Director

**SUBJECT:** Extended use of currently approved, non-Single Tier compliant domestic labels

### I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants that the use of domestic labels that are not compliant with title 9, *Code of Federal Regulations* (9 CFR), part 112; APHIS Rule 2011-0049 (Single Label Claim for Veterinary Biological Products); and APHIS Rule 2008-008 (Labeling and Packaging) may be extended until April 30, 2023. Extended use of currently approved labels will only be allowed when all necessary submissions to meet the 9 CFR 112 requirements of incorporating APHIS Rule 2011-0049 and APHIS Rule 2008-008 have been met.

### II. BACKGROUND

The Center for Veterinary Biologics (CVB) implemented the revised regulations of 9 CFR 112 in Notice 16-15 and then later granted an extension to the implementation date in Notice 19-14. Additionally, CVB had further extended the use of currently approved labels through April 30, 2022, if firms had met the requirements of APHIS Rule 2011-0049 and APHIS Rule 2008-008.

### III. ACTION (or POLICY)

The COVID-19 pandemic has continued to cause unexpected supply chain issues related to accessing vials, containers, cartons, and labeling materials used for labeling final product. Because of these delays, CVB will grant an extension, upon a firm's request, to use currently approved labels through April 30, 2023. Firms wanting this extension should submit a letter to CVB requesting the extension for specific label(s) and include a list of the specific Label Number(s).

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Submit requests to:

Center for Veterinary Biologics (CVB)  
Policy, Evaluation, and Licensing  
National Centers for Animal Health (NCAH)  
1920 Dayton Avenue  
P.O. Box 844  
Ames, IA 50010

Authorized NCAH portal users should submit requests via the portal.

Approval of these requests will be contingent upon CVB receipt of all necessary submissions to meet APHIS Rule 2011-0049 and APHIS Rule 2008-008.

**IV. IMPLEMENTATION/ APPLICABILITY**

This policy is effective immediately.