



Comments Due June 6, 2005

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. DRAFT-004

Subject: Label Requirements for the Products Under Conditional Licenses

To: Biologics Licensees, and Applicants  
Directors, Center for Veterinary Biologics

### I. PURPOSE

This notice informs licensees and applicants of current Center for Veterinary Biologics policy regarding efficacy and potency statements and other label requirements for products under conditional United States Veterinary Biological Product Licenses.

### II. BACKGROUND

As specified in Title 9, Code of Federal Regulations (9CFR), Part 102.6, products may be granted a conditional license in order to meet an emergency condition, limited market, local situation, or other special circumstance. In accordance with 9CFR 102.6(c), labeling for the product may be required to contain information on the conditional status of the license. Labels on conditionally licensed products should be distinctly different from labels on products that are fully licensed so that the consumers are not misled into believing that the conditionally licensed products are equivalent to fully licensed products. The requirements listed below are designed to inform the purchaser of the status of the efficacy and/or potency of conditionally licensed products.

### III. POLICY

Conditionally licensed shall be labeled as follows:

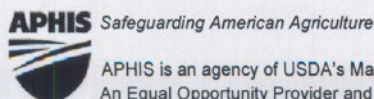
1. The following disclosure statement should be printed on the label:

“Notice! This product license is conditional. Efficacy and/or potency of this product have not been fully demonstrated.”

2. The disclosure statement should appear in a prominent position on the label, preferably under the True Name of the product. The font size should be larger and bolder than the rest of the label text (except the True Name).

3. A statement regarding revaccination, similar to the following, should be included:

“Duration of immunity for this product has not been evaluated; consultation with a veterinarian is recommended.”



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4. Labels for conditionally licensed products should be black and white; no other color label is permitted.

5. No Trade Names are permitted for any conditional license.

**IV: ACTION:**

All labels and promotional materials of products with conditional licenses issued or re-issued subsequent to June 9, 2005, should conform to this guideline.

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics