



March 4, 2005

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-07

Animal and Plant
Health Inspection
Service

Subject: Biologics for Reduction of Colonization and/or Shedding in Animals

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
 Veterinary Services Management Team
 Directors, Centers for Veterinary Biologics

Center for Veterinary
Biologics

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

The purpose of this notice is to inform interested parties of a change in United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) policy regarding licensing requirements for veterinary biological products with a claim of reduced colonization and/or shedding of organisms that may not cause significant clinical disease in animals, but have the potential to adversely impact the management or care of the animal by causing the animal to be a disease carrier.

I. **BACKGROUND**

Title 9 of the Code of Federal Regulations, Part 101.2 states, “The term biological products, also referred to as biologics, biologicals, or products, shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in **the treatment of animals** and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.” Part 101.2(a)(3) also states, “The term treatment shall mean the prevention, diagnosis, **management**, or cure of **diseases of animals**.” To this end, and for the purposes of this notice, managing diseases of animals can include managing a carrier state of a disease.

Historically, products whose primary purpose is to reduce or eliminate a carrier state have not been interpreted to fall under the jurisdiction of the Virus-Serum-Toxin Act, even when those products otherwise met the definition of a biologic. APHIS now proposes to interpret its authority to treat or manage an animal disease to include the carrier state for some pathogens.

II. **GUIDELINES**

In response to requests from industry, the APHIS and the United States Department of Health and Human Services, Food and Drug Administration (FDA) have agreed that the jurisdiction for animal vaccines targeted at the reduction or elimination of a carrier state of organisms that can infect other animals (even if that infection is only rarely associated with significant clinical disease in animals), will lie with APHIS as long as certain criteria are met.



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Those criteria include:

1. Products must be indicated for administration to animals only, and must act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.
2. Label claims and advertising must contain only factual statements supported by data (e.g., as an aid in the reduction of colonization and/or shedding). No food safety or human health claims, either implicit or explicit, would be allowed by APHIS. Products with such claims would fall under the authority of the FDA and require their approval.
3. The products will be required to show significant, substantively meaningful, and clinically relevant efficacy as defined by APHIS. For claims of reduction of colonization and/or shedding, products must demonstrate the ability to cause a substantial decrease in number of animals colonized and/or numbers of organisms shed by vaccinated animals.

/s/ Richard E. Hill, Jr.

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