



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. 23-12

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

FROM: Dr. David White
Acting Director

SUBJECT: Issuance of a Conditional License for Canine Parvovirus Monoclonal Antibody

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Elanco US Inc., Establishment No. 196, Fort Dodge, Iowa, for the manufacture and distribution of Canine Parvovirus Monoclonal Antibody.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in title 9, *Code of Federal Regulations*, part 102, regarding the licensing of veterinary biological products provide that a conditional veterinary biological product license may be issued to meet an emergency condition, limited market, local situation, or special circumstance. The special circumstance addressed here is to treat disease in dogs caused by canine parvovirus 2b.

Conditionally licensed products are required to be pure, safe, and have a reasonable expectation of efficacy. This conditional license was issued on the basis that the licensee has demonstrated that the product has a reasonable expectation of efficacy. APHIS will evaluate their progress throughout the next year. The conditional license will expire two years from the date of the license.