



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 14-12

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

FROM: Byron E. Rippke /s/ *Byron E. Rippke*
Acting Director

SUBJECT: Issuance of a Conditional License for Porcine Epidemic Diarrhea
Vaccine

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Harrisvaccines Inc., Establishment No. 592, Ames, Iowa, for the manufacture and distribution of Product Code 19U5.D0.

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 the absence of other biological products used for control of disease in swine caused by Porcine Epidemic Diarrhea Virus.

Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy. This conditional license was issued following acceptance of data supporting the product has demonstrated a reasonable expectation of efficacy, is safe under normal conditions of use in the field, and has acceptable purity. The conditional license will expire 2 years from the date of the license. APHIS will evaluate the firm's progress throughout the next 2 years toward regular licensure in order to consider reissuance of the conditional license.