Summary of Studies Supporting USDA Product Licensure

Establishment Name	Colorado Serum Company
USDA Vet Biologics Establishment Number	188
Product Code	9360.00
True Name	Caprine Serum Fraction Immunomodulator
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Pulmo-Clear - No distributor specified Pulmo-Clear - Professional Biological Company
Date of Compilation Summary	March 07, 2023

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Caprine Serum Fraction, Immunomodulator
Study Purpose	To demonstrate efficacy of product against lower respiratory disease in equines.
Product Administration	
Study Animals	Equine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.
USDA Approval Date	April 29, 2002

Study Type	Safety
Pertaining to	Caprine Serum Fraction, Immunomodulator
Study Purpose	Demonstrate safety of product in healthy equines
Product Administration	Two doses IM, seven to ten days apart
Study Animals	Two hundred and forty-eight equines, included in eleven studies, were evaluated. Equines of various breeds and both sexes from various locations in Midwestern states of Texas, Arkansas, Oklahoma, and Montana were used. Test animal ages at first product administration: 8 mo. 28 head 8 mo. to 2 yr. 87 head Over 2 yr. 133 head
Challenge Description	
Interval observed after challenge	Observation following each dose: 7 days. Observation included change in appetite, abscesses, swelling and soreness at inoculation site.
Results	Number of Equines exhibiting local reactions associated with product administration. Reaction / 7 days after 1st Dose / 7 days after 2nd Dose / 7 days after 3rd Dose None: 223 / 202 / 58 Slight [1]: 21 / 34* / 21 Moderate[2]: 1 / 9* / 11 Pronounced[3]: 3 / 2* / 6 Total No. in test: 248 / 247** / 96*** [1]One of the following lasting less than three days after administration: tenderness at injection site, local heat at injection site, raised area less than six inches in diameter, limb edema [2][1]One of the following lasting less than seven days after administration: tenderness at injection site, local heat at injection site, raised area less than six inches in diameter, limb edema [3]One of the following lasting less 7-14 days after administration: tenderness at injection site, local heat at injection site, raised area less than six or greater than six inches in diameter, limb edema * All reactions resolved by Day 14 after administration ** One animal removed from test – unrelated to product as affirmed by licensee *** Some animals were administered a third dose based on the veterinarian attending the farm at the time
USDA Approval Date	April 29, 2002