

# Equine West Nile Virus Vaccine

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# West Nile Virus Vaccine, Killed Virus

- ◆ Indications: For use in healthy horses as an aid in the prevention of disease of WNV.
- ◆ Administration: 1 mL intramuscularly, second dose 3 to 6 wks. after the first dose.
- ◆ USDA issued Conditional license August, 2001 - Ft. Dodge Animal Health, Inc.

# Requirements for Conditional License, Title 9, Code of Federal Regulations, Part 102.6

- ◆ to meet an emergency condition
- ◆ limited market, local situation or other special circumstance
- ◆ an expedited procedure
  - assures purity and safety
  - reasonable expectation of efficacy

# Conditional License Requirements

- ◆ Preparation is limited to a predetermined time period, usually 1 year, which is specified at the time of issuance
- ◆ Prior to termination, licensee may request reissuance
- ◆ Reissuance is considered if licensee has demonstrated acceptable progress toward completion of host animal efficacy and potency test studies.
- ◆ After consideration, Administrator will either reissue license or allow it to terminate.

# Conditional License Requirements

- ◆ Distribution in each State is limited to authorized recipients designated by proper State officials under such additional conditions as these authorities may require.
- ◆ All labels will contain a statement that the product license is conditional and that efficacy and potency studies are in progress.
- ◆ Trade names for the product may not be used.

# FDAH WNV Vaccine, Killed Virus

- ◆ NVSL equine isolate
- ◆ Satisfactory completion of purity and laboratory/field safety testing
- ◆ “Reasonable” expectation of efficacy based on host animal serology results
- ◆ USDA confirms purity results, inactivation testing, and laboratory safety results.
- ◆ USDA accepts field safety data as sufficient to issue conditional license.

# Field Safety Trials

- ◆ Vaccine administered according to label directions (2 doses IM, 3 - 6 wks. Apart) under field conditions.
- ◆ Two serials of product were used in eight states, 10 trial sites --> approx. 650 horses vaccinated.
- ◆ Due to emergency situation (FL), preliminary field safety data for 197 horses was submitted to USDA to justify issuance of conditional license and approved.
- ◆ Post licensure the completed FST results were approved by USDA.

# FST Horses - Serology Results

- ◆ Plaque reduction neutralization testing was performed (PRNT) on at least 20% of all participating horses.
- ◆ PRNT of a sample reported as highest dilution that achieves at least 90% plaque reduction.
- ◆ Vaccination with 2 doses elicited an antibody response of neutralizing antibody titer of greater than or equal to 5 (range 5 - 1280) at approx. 2-3 wks. post second vaccination.
- ◆ Vaccinated horses do not develop an IgM response after either the 1st or 2nd dose; only IgG response has been detected.



# Firm Studies in Progress

- ◆ Challenge model has been developed
- ◆ Completed first efficacy trial --> preliminary results look favorable.
- ◆ Working on adding WNV to large combination vaccine.

# Adverse Reports

- ◆ CVB has had no reports of any adverse events regarding the WNV Vaccine, Killed Virus product.