§ 113.205  Wart Vaccine, Killed Virus.

Wart Vaccine, Killed Virus, shall be prepared from virus-bearing epidermal tumors (warts) obtained from a bovine. Each serial shall meet the requirements prescribed in this section and any serial found unsatisfactory by a prescribed test shall not be released.

(a) Purity. Final container samples of completed product shall meet the requirements prescribed in §113.200(c)(1) and (3).

(b) Safety. Bulk or final container samples of completed product shall meet the requirements for safety as prescribed in §§113.33(b) and 113.38.

(c) Formaldehyde content. Bulk or final container samples of completed product shall meet the requirements for formaldehyde content as prescribed in §113.200(f).

(d) Potency and efficacy. The efficacy of wart vaccine has been demonstrated to the satisfaction of Veterinary Services as being a valuable biological product. The inherent nature of the product precludes the possible development of serial to serial potency tests and none is required: Provided, That,

(1) The vaccine shall be a tissue extract representing at least 10 percent weight to volume suspension of wart tissue; and

(2) The vaccine shall be limited to use in the prevention of warts in cattle. Labeling recommendations shall be in accordance with §112.7(i).

§ 113.206  Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.

Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Each serial or subserial shall meet the requirements prescribed in this section and the general requirements prescribed in §113.200, except those in §113.200(d). Any serial or

§ 113.207  Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.