

1237; telephone (301) 734-8400; fax (301) 734-8910.

SUPPLEMENTARY INFORMATION: A veterinary biological product regulated under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*) must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in 9 CFR part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstance. The special circumstance addressed here is the current raccoon rabies epizootic in the United States. The product being issued a conditional license is intended for vaccinating raccoons against rabies. No other licensed product is currently available for this purpose. The vaccination of raccoons is proposed to limit the further spread of the raccoon rabies epizootic, and to prevent the spread of rabies to domestic animals and to humans. Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy.

In determining whether to issue a conditional license for the veterinary biological product referenced in this notice, the Animal and Plant Health Inspection Service (APHIS) conducted a risk analysis to assess the product's potential effects on the safety of animals, public health, and the environment. Based on that risk analysis, APHIS has prepared an environmental assessment. APHIS has concluded that issuance of a conditional veterinary biological product license for the veterinary biological product referenced in this notice will not significantly affect the quality of the human environment. Based on the finding of no significant impact, we have determined that there is no need to prepare an environmental impact statement.

An environmental assessment and a finding of no significant impact have been prepared for the issuance of a conditional veterinary biological product license for the following veterinary biological product: Rabies Vaccine, Live Vaccinia Vector; Code 1901.R0; to be issued to Rhone Merieux, Inc., Establishment License No. 298. This recombinant rabies vaccine is intended for vaccinating raccoons against rabies, and is not intended for use in pets. The conditional license restricts the use of this product to State or Federal Government agencies administering wildlife rabies control programs. The availability of the

recombinant rabies vaccine for use in rabies control programs may be useful in limiting the spread of the current rabies epizootic in the United States.

A conditional license has been issued on the basis that the product has been demonstrated to be pure and safe, and to have a reasonable expectation of efficacy. The product has not met the efficacy requirements of title 9, Code of Federal Regulations, § 113.312 for rabies vaccines; however, a reasonable expectation of efficacy has been demonstrated in the studies that have been conducted to date. The efficacy of this recombinant rabies vaccine will be further evaluated during the conditional license period. The State and Federal Government agencies using the rabies vaccine will be provided with detailed instructions for safely using the recombinant vaccine. These instructions include continued use of the following mitigative procedures that have been implemented for the field tests previously conducted with this product:

1. Public education efforts, including education efforts directed at school-aged children, should be conducted prior to distributing the baits containing the recombinant rabies vaccine. Warning labels should be attached to the baits to minimize the possibility of accidental exposure of members of the local populations in the areas where the vaccine-laden baits are distributed. The warning labels should clearly identify the recombinant vaccine and list the phone number for the local public health authorities. The public education efforts should be conducted prior to distributing the baits and should include newspaper articles, local television reports, and the distribution of brochures and posters. Public information meetings may also be used. In addition, when the baits are distributed, signs should be posted at the periphery and at strategic points within the distribution area notifying visitors of the rabies control efforts and warning them not to disturb the vaccine-laden baits.

2. The local public health authorities in the areas where the recombinant rabies vaccine is used should be notified prior to the distribution of the baits. The public health authorities should be instructed to inform the authorizing State or Federal Government agency of any reported human contacts with the vaccine-laden baits. Individuals who may have been exposed to the vaccine should be examined for any adverse reactions or clinical signs of orthopoxvirus infection, and have blood samples drawn and analyzed for the presence of antibodies of rabies and/or vaccinia.

3. The personnel conducting the rabies control programs should be trained in the appropriate precautions and techniques for assembling, handling, and distributing the vaccine-laden baits. These personnel should be encouraged to be vaccinated against vaccinia, as recommended by the U.S. Public Health Service [Morbidity and Mortality Weekly Report; Recommendations and Reports; Vaccinia (Smallpox) Vaccine, Recommendations of the Immunization Practices Advisory Committee (ACIP), Vol. 40, pp. 1-10 (1991)], and also be vaccinated against rabies. All personnel should be non-pregnant adults at least 18 years of age, who are free of any known immunosuppressive conditions. Regular blood samples should be collected from the personnel and monitored for the presence of rabies and vaccinia antibodies.

4. The filling of the liquid vaccine into ampules for assembly into the baits should be conducted according to Biosafety Level-2 (BL-2) criteria [CDC-NIH Manual: Biosafety in Microbiological and Biomedical Laboratories, Third Edition (1993) pp. 18-24].

5. Any adverse reactions observed in the areas where the recombinant rabies vaccine is used should be reported to the licensed manufacturer, who will forward this information to Veterinary Biologics, APHIS.

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS NEPA Implementing Procedures (60 FR 6000-6005, February 1, 1995).

Done in Washington, DC, this 20th day of April 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

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