NORMATIVE INSTRUCTION No. 69, OF DECEMBER 13, 2002

THE SECRETARY OF ANIMAL AND PLANT HEALTH, OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY, in the use of the attribution conferred on him by art. 83, item IV, of the Internal Regulations of the Secretariat, approved by Ministerial Ordinance No. 574, of December 8, 1998, in view of the provisions of art. 28, of the Regulation for Inspection of Veterinary Use Products, approved by Decree No. 1,662, of October 6, 1995,

Considering that the commercialization and distribution of products for veterinary use are the responsibility of the private sector, in compliance with specific regulations;

Considering the objectives, goals and activities of the National Herbivore Rabies Control Program (PNCRH), provided for in the "Technical Norms for Domestic Herbivores Rabies Control", approved by Normative Instruction No. 5, of March 1, 2002;

Considering the need to optimize the storage and distribution system of rabies vaccines for herbivores throughout the National Territory;

Considering the need to have updated statistical data on the distribution of this immunogen to support the actions of the Coordination of Surveillance and Sanitary Programs and the Coordination of Inspection of Veterinary Products, resolves:

- Art. 1. Determine the use of a (holographic) guarantee seal on all herbivore rabies vaccine vials of the batches approved and released for commercialization by the Ministry of Agriculture, Livestock and Supply, in order to ensure their compliance with the norms of control of the production and marketing of vaccines against herbivore rabies.
- Art. 2. The guarantee seal, to be used by manufacturing laboratories and importing establishments of vaccines against herbivorous rabies, must be previously approved by the Department of Animal Health, of this Secretariat, and will have characteristics of resistance and inviolability.
- Art. 3. From the date of entry into force of this Normative Instruction, the marketing and use of vaccines against herbivore rabies will only be authorized when the vials contain the guarantee seal affixed to the labeling, except for batches of vaccines approved, released and exposed to sale in commercial establishments prior to the entry into force of this Normative Instruction, which may be marketed until the expiration of the product's expiration date.
- Art. 4. This Normative Instruction enters into force 60 (sixty) days after the date of its publication.