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MEMORANDUM CIRCULAR

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SUBJECT: AMENDMENT OF THE GUIDELINES FOR THE CONDUCT OF LOCAL STUDIES/FIELD TRIALS ON VETERINARY BIOLOGICAL PRODUCTS

In our desire to clearly define the requirements, guidelines and procedures in the conduct of local studies or field trials maybe permitted by this office.

1. The veterinary biological products shall undergo local studies or field trials for safety and efficacy for the following:
 - 1.1. Products of which vaccine strain are different from those registered in the country based on the evaluation of Veterinary Biologics Technical Evaluation Committee (VBTEC);
 - 1.2. Products with a new combination;
 - 1.3. Products that are derived from biotechnology and other advanced innovations; and
 - 1.4. Products that are locally produced.
2. The company shall develop a field trial protocol based on Field Trial Protocol Format for Safety and Efficacy of Veterinary Biological Products for Registration (Appendix A).
3. The protocol shall be submitted to the Animal Feeds, Veterinary Drugs and Biologics Control Division (AFVDBCD) for review, clearance and endorsement to the Director of the Bureau of Animal Industry (BAI) for approval.
4. Once the protocol is approved, Memorandum of Undertaking for the Conduct of Field Trial (Appendix B) between the company and BAI must be duly accomplished in two (2) copies and shall be forwarded to BAI for approval then back to the company for notarization. After notarization, the company will submit one (1) copy to AFVDBCD.
5. The Field Trial shall be conducted in at least three (3) farms at different geographical locations which **HAVE BEEN DIAGNOSED POSITIVE** by **Animal Disease Diagnosis and Reference Laboratory (ADDRL)** of the disease for which the product is intended for use.
6. The company shall have the option to choose the farm trial sites in accordance with approved guidelines.
7. The experimental animals to be used shall represent the ages and husbandry practices. (if applicable Good Animal Husbandry Practices (GAHP) compliant for which the product is indicated for)

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