[DOH DEPARTMENT OF HEALTH ADMINISTRATIVE ORDER NO. 118, s. 1992, March 03, 1992]

RULES AND REGULATIONS ON THE PROCESS OF REVIEW AND EVALUATION OF QUESTIONED VETERINARY DRUGS OR VETERINARY DRUG COMBINATIONS

Pursuant to Section 3(c) and 26(a) of Republic Act No. 3720, as amended, the following rules and regulations are hereby promulgated to govern the review, evaluation and subsequent banning from the market of drugs or drug combinations which have been found unsafe, ineffective or of doubtful therapeutic value.

SECTION 1. Definition of Terms —

1.1 Veterinary Drugs refer to: (1) articles recognized in the current official United States Pharmacopeia (USP), National Formulary (NF), official homeophatic pharmacopeia of the United States, official Philippine National Veterinary Drug Formulary (PNVDF), or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in terrestrial and aquatic animals; (3) articles (other than food) intended to affect the structure and function of the animal body; and (4) articles intended for use as a component of any article specified in clauses (1), (2) or (3) but do not include devices or their components, parts or accessories.

1.1.1 Prescription or Ethical Veterinary Drugs and Products refer to any drug preparation that is to be dispensed only upon written order of a duly-licensed veterinarian for the treatment of a condition or a diagnosed disease of animals. Such preparation are labelled Rx.

1.1.2 Non-prescription Veterinary Drugs or Over-the-Counter Veterinary Drugs (OTC) or Self-Service Veterinary Drugs (SS) refer to drug preparations that can be approved for animal use, even without the written order of a duly-licensed veterinarian.

1.2 Veterinary Pharmaceutical refers to the finished dosage form that contains the active ingredient(s), generally but not necessarily in association with inactive ingredients.

1.3 Banning refers to the act to prohibit the importation, manufacture, distribution, labelling, advertising and sale of a veterinary drug and product determined to be unsafe or ineffective as a consequence of veterinary drug combination, shall be removed from the registry.

SECTION 2. Procedure for Review and Evaluation —

2.1 The process of review and evaluation is initiated when reliable scientific