[BAI DEPARTMENT OF AGRICULTURE ADMINISTRATIVE ORDER NO. 3, S. 1992, March 03, 1992]

DEPARTMENT OF HEALTH ADMINISTRATIVE ORDER NO. 118, S. 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 information indicates that a veterinary drug or combination of veterinary drugs is unsafe or ineffective or when there is a complaint by any party with substantial interest. The complaint should be properly documented and should include the following information:

2.1.1 proper identification of the veterinary drug or combination of veterinary drugs.

2.1.2 description of reason to question its safety, efficacy, or therapeutic value.

2.2 Process of Hearing —

2.2.1 BFAD/BAI will publish the order and date of public hearing, which shall not be later than fifteen calendar days from the date of the publication of such order.

2.2.2 The affected veterinary drug establishment must justify the continued BFAD/BAI registration of the veterinary drug and product on the basis of safety, efficacy, and therapeutic value of active ingredients it contains. All interested parties may present additional documentary evidence to clarify and supplement their position papers within thirty (30) calendar days from the date of the first public hearing. Verified and authentic evidence and the position papers shall constitute the direct evidence on the questioned veterinary drug.

2.2.3 All parties are entitled to cross-examine by the witnesses, that may be presented by the interested parties and affected veterinary drug establishment/s or witnesses who may be called by BFAD/BAI to establish the authenticity, degree of accuracy and/or propriety of the reports or documents submitted in evidence or to testify to any material fact. For this purpose, BFAD/BAI shall require all parties concerned to submit a list of these witnesses and the time frame within which they will testify. This list and the time frame shall be strictly followed. Any witness not in the list shall not be allowed to testify. Failure to testify within the approved time frame shall be deemed a waiver on the part of the interested party.

2.2.4 The BFAD/BAI may call upon a panel of experts, if necessary, to provide additional informations and to evaluate submitted evidence. These experts shall advise BFAD/BAI on the matter.

2.2.5 The evidences presented in the public shall be evaluated by BFAD/BAI on the basis of current standards for safety, efficacy and therapeutic value as defined in Joint Administrative Order, Department of Health No. 111-A s. 1991 and Department of Agriculture No. 33 s. 1991, Rules and Regulations on Veterinary Drugs and Products.

2.2.6 The BFAD/BAI shall make recommendation to the Secretary of Health/Secretary of Agriculture within thirty (30) days from termination of hearing.

2.2.7 The Secretary of Health/Secretary of Agriculture shall decide the final action to be taken and shall duly inform the parties concerned of the decision taken.

2.3 This procedure of review and evaluation does not preclude however to BFAD/BAI

from submitting a recommendation to immediately ban a veterinary drug and a veterinary product in cases where there is a clear finding of serious or lethal toxicity constituting undue risk to animal health and public safety.

2.4 BFAD/BAI shall submit its finding and recommendation, together with records of substantial evidence to the Secretary of Health/Secretary of Agriculture for immediate action.

SECTION 3. Separability Clause — In case any provision of these rules and regulations is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and in effect.

SECTION 4. Repealing Clause — This Order shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

Adopted: 3 Mar. 1992

(SGD.) SENEN C. BACANI
Secretary of Agriculture

(SGD.) ANTONIO Q. PERIQUET, M.D.
Secretary of Health

ANNEX A
(LIST A)

List of Pharmaceutical Products Classified as Prohibited Drugs or Regulated Drugs by the Dangerous Drugs Board

Prohibited Drugs

1.	Alfentanil	- Rapifen Injectable
2.	Codeine (as sulfate)	- Codeine Sulfate H.T. - Codeine Sulfate T.T.
3.	Codeine (as phosphate) - Dolo	-Adamon Suppository - Dolo-Adamon Tablet
4.	Dihydrocodeine	- Not available in the market
5.	Fentanyl (as citrate)	- Sublimaze Injectable
6.	Fentanyl (as citrate/Droperidol)	- Innovar Injectable
7.	Hydrocodone (Dihydrocodeinone) (as bitartrate)	- Deka Syrup - Raminon Syrup
8.	Hydrocodone	- Tussionex Suspension

(Dihydrocodeinone) (Phenyltoloxamine)	
9. Hydrocodone (Dihydrocodeinone) (as bitartrate) plus Pyrllamine (as maleate)/ Sodium Citrate/Ammonium Chloride/Potassium Guaiacolsulfonate	- Codevite Syrup
10. Hydrocodone (Dihydrocodeinone) (as bitartrate) plus Pyrilamine (as maleate) Homatropine (as methylbromide)/ Phenylephrine (as hydrochloride) Ammonium Chloride	- Endotussin Syrup
11. Morphine (as sulfate)	- Morphine Sulfate H.T. - Morphine Sulfate Ampul - Morphine Sulfate Tablet
12. Morphine (as sulfate)/Atropine	- Morphine with Atropine
13. Opium	- Brown Mixture Tablet - Brown Mixture Liquid
14. Opium/Alcohol	- Elixir Paregoric
15. Pethidine (Meperidine) (as hydrochloride)	- Demerol Ampul - Demerol Tablet - Demerol Vial

Regulated Drugs

A. Available in the Market

1. Amobarbital* (as sodium)	- Amytal Sodium Ampul - Amytal Sodium Capsule - Amytal Sodium Tablet
2. Amphetamine	- Benzedrine Tablet - Daprisal Tablet
3. Aprobarbital, Barbital, and Phenobarbital	- Plexonal
4. Chloral Hydrate	- Noctec