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DEPARTMENT OF HEALTH ADMINISTRATIVE ORDER NO. 118, S. 1992

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

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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

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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)

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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 (Dihydrocodeinone)
(Phenyltoloxamine) - Tussionex Suspension

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

5. Dexamphetamine - Dexedrine Spansule

6. Ephedrine (excluding exempt preparations)

7. Ethinamate - Valamin Tablet

8. Flunitrazepam - Rohypnol

9. Nitrazepam - Mogadon

10. Paraldehyde - Paraldehyde Ampul

11. Pentazocine (as hydrochloride) - Susegon Tablet

12. Pentazocine (as base) - Susegon Ampul

13. Pentothal (as sodium) - Pentothal Sodium Vial
- Thiopental Sodium Vial

14. Propoxyphene (as hydrochloride) - Doloxene Plain Tablet

15. Propoxyphene (as napsylate),
Aspirin, and Caffeine - Doloxene Compound-65

16. Propoxyphene (as napsylate)/
Paracetamol - Dologesic-32

17. Pseudoephedrine (excluding exempt preparations)

B. Not available in the Market

1. Amobarbital/Dexamphetamine - Dexamyl Spansule No. 1

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2. Butabarbital - Butisol Sodium Tablet
- Circuline Forte Tablet

3. Ethchlorvynol - Placidyl Capsule

4. Hydrocodone (Dihydrocodeinone)/ Pentobarbital - Calcidrine Syrup

5. Mecloqualone - Nubarene Tablet

6. Methamphetamine - Desoxyn Tablet
- Drinalfa Vial

7. Methaqualone/Diphenhydramine (as hydrochloride) - Mandrax Tablet

8. Methylprylon - Moludar Tablet

9. Pentobarbital (as sodium) - Nembutal Sodium Vial

10. Pipradrol - Gadexyl Tablet

11. Secobarbital - Seconal Sodium
Capsule

ANNEX B
(LIST B)

List of Veterinary Drugs and
ProductsRequiring Strict Precaution in Prescribing,
Dispensing and Use

1. Acepromazine : Tablet/Injectable

2. Aminophylline : Suppository/Tablet

3. Amitraz : Pour on

4. Amphotericin B : Injectable

5. Azaperone : Injectable

6. Betamethasone : Tablet

7. Bunamidine : Tablet

8. Carbadox : Premix

9. Chlorambucil : Tablet

10. Chlorampenicol : Capsule/Injectable

11. Chlorpropamide : Tablet

12. Colistin : Injectable

13. Cyclophosphamide : Tablet

14. Dexamethasone : Tablet

15. Dexamethasone Acetate : Injectable

16. Diazepam : Tablet

17. Dichlorvos : Capsule/Granules

18. Diethylstilbestrol (DES) : Injectable

19. Digitoxin : Tablet

20. Digoxin : Tablet

21. Dihydrostreptomycin : Injectable

22. Dimetridazole : Injectable

23. Diminazine : Injectable

24. Epinephrine : Injectable

25. Erythromycin : Injectable

26. Estrogens, Conjugated : Injectable

27. Ethinylestradiol : Tablet

28. Ethosuximide : Capsule

29. Furazolidone : Suspension/Tablet

30. Furosemide : Tablet/Injectable

31. Gentamicin : Injectable

32. Halquinol : Premix

33. Hydrochlorothiazide : Tablet

34. Hydrocortisone : Injectable

35. Imidocarb : Injectable

36. Insulin : Injectable

37. Ivermectin : Tablet/Injectable

38. Ketamine : Injectable

39. Lasalocid : Premix

40. Levamisole : Injectable

41. Lindane
: Pour On

42. Lorazepam : Oral

43. Melarsonyl : Injectable

44. Mundane : Tablet

45. Menadione Sodium Bisulfate : Tablet

46. Mephenytoin : Tablet

47. Methdilazine Hydrochloride : Tablet

48. Methotrexate : Tablet

49. Methylergometrine (Methylergonovine) Maleate : Tablet

50. Metronidazole : Tablet

51. Monensin
: Premix

52. Neomycin : Injectable

53. Niclosamide : Tablet

54. Nitrofurantoin : Capsule/Suspension/ Tablet

55. Olaquindox : Premix

56. Ouabain : Injectable

57. Oxytetracycline (Long-Lasting) : Injectable

58. Oxytocin : Injectable

59. Pancuronium : Injectable

60. Perphenazine : Suppository/Syrup/ Tablet/Or Tablet

61. Phynylbutazone : Capsule/Tablet

62. Phenytoin : Suspension

63. Phenytoin Sodium, Extended : Capsule

64. Phenytoin Sodium, Prompt : Capsule

65. Praziquantel : Tablet

66. Probenecid : Tablet

67. Procainamide Hydrochloride : Capsule/Tablet/Or Tablet

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68. Propionyl Phenothiazine : Injectable

69. Prostaglandin F2 Alpha : Injectable Powder

70. Pyrazinamide : Tablet

71. Quinidine Sulfate : Capsule/Tablet or Tablet

72. Salinomycin : Premix

73. Spironolactone : Tablet

74. Streptomycin : Injectable

75. Succinylcholine : Injectable

76. Sulfadiazine; Sulfamerazine; Sulfamethazine : Tablet

77. Sulfamethizole : Suspension/Tablet

78. Sulfisoxazole : Suspension/Tablet

79. Suramin : Injectable

80. Theophylline (Sprinkles/Suspension/Or Tablet) : Tablet/or Capsule

81. Thiacetarsamide : Injectable

82. Thioridazine Hydrochloride : Tablet

83. Thyroglobulin : Tablet

84. Tolbutamide : Tablet

85. Triamcinolone : Tablet

86. Xylazine : Injectable

LIST C

A. All Anti-Infectives Except Topical Forms
B. All Acaricides
C. All Insecticides Except Carbamates, Pyrethioids and Repellants
D. All Biologicals and Immunologicals
E. All Cardiovascular Drugs
F. All Hormones
G. All Antineoplastics
H. All Parenteral Fluids
I. All Corticosteroids
J. All Euthanizing Agents
K. All Anabolics

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[*] Local suppliers no longer carry these drugs but are still available in some drugs and hospital pharmacies.

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