Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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Administrative Order
No. 64 S. 1989

Subject: Amendments of A.O. No. 55 s. 1988 Otherwise Known As Requirements for Labelling Materials of Pharmaceutical Products

WHEREAS, there is a need to harmonize the provisions of A.O. 55 s. 1988 on Requirements for Labelling Materials of Pharmaceutical Products with the provisions of A.O. 62 S. 1989 on Prescribing Requirements;

WHEREAS, some drug establishments through their association have requested that the starting date for requiring the new labels under A.O. No. 55 be postponed from April 1, 1989 to July 1, 1989;

WHEREAS, the Industry has signified that the labelling requirements for blister packs to put the product name, strength and expiry date for every two units are physically not posible.

WHEREAS, in view of many new labels to be designed, approved and printed, more lead time is required if drug establishments would be able to comply with the provisions of A.O. No. 55.

NOW THEREFORE, A.O. 55 s. 1988 on Requirements for Labelling Materials of Pharmaceutical Products is hereby amended as follows:

Section 1. Section 2.1.15 shall read as follows:

2.1.15 Caution for Prescription Drugs

All prescription or Rx drug products shall carry the following caution

2.1.15.1 For any product belonging to List A, herein identified as Annex I:

"Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription (List A)"

2.1.15.2 For any drug product belonging to List B, herein identified in Annex 2:

"Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription (List B)"

2.1.15.3 For all other prescription drug products:

"Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription".

Section 2. Sections 3.1.4 and 3.1.5 are hereby merged and amended to read as follows

3.1.4 Products containing two or more active ingredients, shall have generic names as determined by BFAD. All provisions above referring to generic names shall be applicable to these products as well . The starting date for the use of these generic names on the label shall be in accordance with a schedule to be determined by BFAD.

Section 3. Section 10.2 is hereby amended as follows:

10.2 For products contained in a strip or blisters packs, the requirement of 2.1.1, strength, expiry date, company name and batch numbers must appear for every standard strip.

Section 4. Section 17 is hereby amended to read as follows:

Section 17 Effectivity

This regulation shall take effect fifteen (15) calendar days after its publication in two newspapers of general circulation or in the Official Gazette. Provided hovever,(1)that all productions shall be covered by these rules and regulations as soon as the manufacturer or trader is ready but not later than July 1,1989 provided for in 3.1.4 as amended;(2) that drug establishments shall have their new label approved by BFAD starting on the date of the effectivity of these rules and regulations,

provided further, that all drug establishments shall report to BFAD the first batch number of their production which carries the new label. However, those products already in the market bearing the old labels shall be allowed to remain in the market, but not later than December 31, 1989.

Section 5. This order shall take effect immediately upon approval.

Alfredo R.A. Bengzon, M.D.
Secretary of Health

LIST A (ANNEX A)

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

I Prohibited Drugs

1. Brown Mixture Tab.
2. Brown Mixture Lig.
3. Codeine Sulfate H.T.
4. Codeine Sulfate T.T.
5. Demerol Amp.
6. Demerol Tab.
7. Demerol Vial
8. Dolo-Adamon Supp.
9. Dolo-Adamon Tab.
10. Elixir Paregesic
11. Innovar Inj.
12. Morphine Sulfate H.T.
13. Morphine with Atropine
14. Morphine Sulfate Amp.
15. Morphine Sulfate Tab.
16. Sublimaze Inj.
17. Repifen Inj.
18. Codevite Syrup
19. Deka Syrup
20. Endotussin Syrup
21. Raminon Syrup
22. Tussionex Susp.

II Regulated Drugs

1. Amytal Sod. Tablet
2. Amytal Sod. Cap.
3. Amytal Sod. Amp.
4. Benzedrine Tab.
5. Butisol Sod. Tab.
6. Calcidrine Syrup
7. Circuline Forte Tab.
8. Daprisal Tab.
9. Desozyn Tab.
10. Dexamyl Spansule No. 1
11. Dexedrine Spansule
12. Doloxene Compound-65
13. Doloxene Plain Tab.
14. Drinalfa Vial
15. Gadexyl Tab.
16. Mandrax Tab.
17. Mogadon
18. Nembutol Sod. Vial
19. Noctec
20. Noludar Tab.
21. Nuberene Tab.
22. Paraldehyde Amp.
23. Pentothal Sod. Vial
24. Placidyl Cap.
25. Plexonal
26. Robypnol
27. Seconal Sod. Cap.
28. Sosegon Amp.
29. Sosegon Tab.
30. Thiopental Sod. Vial
31. Valamin Tab.

L I S T B (Annex 2)

LIST OF PRODUCTS REQUIRING STRICT PRECAUTION IN PRESCRIBING, DISPENSING AND USE

1. AMINOPHYLLINE : SUPPOSITORY/TABLET
2. AMITRIPTYLINE HYDROCHLORIDE : TABLET
3. BETAMETHASONE : TABLET
4. BUSULFAN : TABLET
5. CHLORAMBUCIL : TABLET
6. CHLORPROPAMIDE : TABLET
7. CHLORTHALIDONE : TABLET
8. CYCLOPHOSPAMIDE : TABLET
9. DEXAMETHASONE : TABLET
10. DEXAMETHASONE ACETATE : INJECTABLE
11. DICUMAROL : CAPSULE/TABLET
12. EPINEPHRINE : INJECTABLE
13. ESTROGENS, CONJUGATED : INJECTABLE
14. ETHINYL ESTRADIOL : TABLET
15. ETHOSUXIMIDE : CAPSULE
16. FURAZOLIDONE : SUSPENSION/TABLET
17. HYDROCHLOROTHIAZIDE : TABLET
18. HYDROCORTISONE : INJECTABLE
19. IMIPRAMINE HYDROCHLORIDE : TABLET
20. MENADIONE : TABLET
21. MENADIONE SODIUM BISULFATE : TABLET
22. MEPHENYTOIN : TABLET
23. METHDILAZINE HYDROCHLORIDE : TABLET
24. METHOTREXATE : TABLET

25. METHYLERGONOVINE MALEATE : TABLET

26. NITROFURANTOIN : CAPSULE/SUSPENSION/TABLET

27. PERPHENAZINE : SUPPOSITORY/SYRUP/TABLET/CR TABLET

28. PHENYLBUTAZONE : CAPSULE/TABLET

29. PHENYTOIN : SUSPENSION

30. PHENYTOIN SODIUM, EXTENDED : CAPSULE

31. PHENYTOIN SODIUM, PROMPT : CAPSULE

32. PROBENECID : TABLET

33. PROCAINAMIDE HYDROCHLORIDE : CAPSULE/TABLET/CR TABLET

34. PYRAZINAMIDE : TABLET

35. QUINIDINE SULFATE : CAPSULE/TABLET/CR TABLET

36. SPIRONOLACTONE : TABLET

37. SULFADIAZINE; SULFAMERAZINE; SULFAMETHAZINE : TABLET

38. SULFAMETHIZOLE : SUSPENSION/TABLET

39. SULFISOXAZOLE : SUSPENSION/TABLET

40. THEOPHYLLINE: CR CAPSULE/ CR CAPSULE (SPRINKLES) / SUSPENSION/CR TABLET

41. THIORIDAZINE HYDROCHLORIDE : TABLET

42. TYROLOBULIN : TABLET

43. TOLBUTAMIDE : TABLET

44. TRIAMCINOLONE : TABLET

45. WARFARIN SODIUM : TABLET