



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOODS AND DRUGS
D.O.H. Compound
Alabang, Muntinlupa, Metro Manila

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BUREAU CIRCULAR
No. 01 s. 1997

TO : **ALL DRUG MANUFACTURERS, TRADERS, AND DISTRIBUTOR IMPORTERS**

SUBJECT : **ENFORCEMENT OF THE REQUIREMENT FOR BIO-AVAILABILITY STUDIES FOR REGISTRATION OF PRODUCTS INCLUDED IN THE LIST B' (PRIME) UNDER DOH - ADMINISTRATIVE ORDER 67 SERIES OF 1989.**

In Annex 1 of A. O. 67 s. 1989 which is entitled Requirement for Registration provides that " Bioavailability/Bioequivalence study for certain drugs as determined by BFAD " is required for Tried and Tested Drug, (ii) Established Drug, and (iii) Pharmaceutical Innovation of Tried and Tested or Established Drug.

Drugs requiring strict precaution in prescribing and dispensing contained in the List-B (Prime) were the drugs identified by BFAD in the process of registration that will be required " Bioavailability/Bioequivalence " studies. However, due the supervening factor that there had yet been no bioavailability testing unit in the country when the A.O 67 s. 1989 became effective, the Bureau did not strictly enforce the said requirement.

The supervening factor no longer exist as of date. As a matter of fact, one of the registered products tested by the Bioavailability Testing Unit at the University of Sto. Tomas under the NDP Cooperation Project of the Philippines and Australia failed to meet the standard of bioavailability. This finding brings forth the fact that there may be registered products which do not or may no longer meet bioavailability standard.

Wherefore, all drug manufacturers, traders, distributor-importers of products contained or identified in the list b' (prime) provided for by BFAD, a copy of which is made part of this circular, are advised that all pending initial and renewal registration of the products aforementioned, as well as all applications for initial and renewal registration of the same, shall henceforth be required to submit bioavailability test with satisfactory results on the products sought to be registered or renewed conducted by any bioavailability testing units here or abroad, duly recognized by the BFAD under the Dept. of Health.

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LIST B' (PRIME)
LIST OF DRUG PRODUCTS WITH REPORTED
BIOAVAILABILITY/BIOEQUIVALENCE PROBLEMS

I. Available in Several Brand Names/ Manufacturers

II. Available as Single Brand

1. AMINOPHYLLINE (THEOPHYLLINE)	suppository/tablet	1. ACEBUTOLOL	tablet/capsule
2. BETAMETHASONE	tablet	2. ACETOHEXAMIDE	tablet
3. CEFALEXIN	capsule/pulvule/caplet suspension/drops	3.AJMALINE	tablet
4. CEFAZOLIN	injectable	4.ALPRENOLOL	tablet/durules/injectable
5. CHLORAMPHENICOL	capsule/suspension (as palmitate) / injectable (as Succinate)	5.AMIODARONE	tablet/injectable
6. CHLORPROMAZINE	tablet/injectable	6.AMITRYPTYLIN	tablet (as hydrochloride)
7. CLOMIFENE (CLOMIPHENE)	tablet	7.ATENOLOL	tablet
8. CLONIDENE	tablet/injectable	8.BEVANTOLOL	tablet
9. CONJUGATED ESTROGENS	tablet/injectable	9.BROMOCRYPTINE	tablet
10. CYCLOPHOSPHAMIDE	tablet	10.BUSULFAN	tablet
11. CYPROTERONE	tablet	11.BUTRIPTYLINE	tablet
12. DEXAMETHASONE	injectable	12.CAPTOPRIL	tablet
13. DIGITOXIN	tablet	13.CARBAMAZEPINE	tablet/syrup
14. DIGOXIN	tablet/elixir/injectable	14.CHLORAMBUCIL	tablet
15. DILTIAZEM	tablet/SA tablet	15.CHLORPROPAMIDE	tablet
16. DISOPHYRAMIDE	capsule/tablet (retard)	16.CLONAZEPAM	tablet
17. EPINEPHRINE (ADRENALINE)	injectable (as HCl)	17.DESLANOSIDE	tablet/(as lanatoside C) / injectable
18.ERYTHROMYCIN	capsule/film tablet/suspension/injectable	18.DIETHYLSTILBESTROL	tablet
19. ETHINYLESTRADIOL	tablet	19.DOSULEPIN (DOTHIEPIN)	tablet/capsule
20. FELODIPINE	ER tablet	20.DROPERIDOL	injectable
21.GLIBENCLAMIDE	tablet	21.DYDROGESTERONE	tablet
22.GLYCERYL TRINITRATE (NITROGLYCERIN)	tablet/patch/ointment	22.ANALAPRIL	tablet
23. HALOPERIDOL	tablet/injectable	23.ETHOSUXIMIDE	capsule
24. HYDROCORTISONE	injectable (as sodium succinate)	24.ETHYLESTRENOL	tablet
25.ISOSORBIDE DINITRATE	tablet/SA tablet/sublingual tablet	25.FLECAINIDE	tablet
26.ISOSORBIDE MONONITRATE	-5- tablet/SR durules	26.FLUOCORTOLONE	tablet
27.LEVOTHYROXINE	tablet	27.FLUOXYMESTERONE	tablet

28.LIOTHYRONINE	tablet	28.FLUPENTIXOL	tablet
29.MAGNESIUM SULFATE	injectable	29. FLUPHENAZINE	injectable
30.METHOTREXATE	tablet (as sodium salt)	30. FLURAZEPAM	tablet
31. METHYLERGOMETRINE (METHYLERGONOVINE)	tablet (as hydrogen maleate)	31.FLUTAMIDE	tablet
32.METHYLPREDNISOLONE	tablet	32.GLICLAZIDE	tablet
33.METOPROLOL	tablet	33.GLIPIZIDE	tablet
34.NIFEDIPINE	tablet / (retard)/capsule tablet	34.GUANFACINE	tablet
35.NORETHISTERONE	tablet	35.IMIPRAMINE	tablet (as hydrochloride)
36.OXPRENOLOL	tablet/SR tablet	36.LABETALOL	tablet
37.PROPRANOLOL	tablet/injectable	37.LITHIUM CARBONATE	tablet
38.PYRAZINAMIDE	tablet	38.MEDROXYPROGESTERONE	tablet
39.QUINIDINE	durules (as sulfate)/capsule (as polygalacturonate)	39.MESTEROLONE	tablet
40.RIFAMPICIN	capsule/tablet/syrup	40.METFORMIN	tablet
41.TESTOSTERONE	capsule	41.MIDAZOLAM	tablet/injectable
42.THEOPHYLLINE	tablet/SR tablet/SR capsule/syrup	42.NADOLOL	tablet
43.TRIAMCINOLONE	tablet	43.NICARDIPINE	tablet
44.VERAPAMIL	tablet/SR tablet/dragees/injectable	44.NITRENDIPINE	tablet
		45.OXANDROLONE	tablet
		46.PERPHENAZINE	suppository/syrup/tablet/Cr tablet
		47.PHENYTOIN	suspension/capsule (as sodium salt)
		48.PINDOLOL	tablet
		49.PRAZOSIN	tablet
		50.PROCAINAMIDE	capsule/tablet/Cr tablet (as HCl)
		51.TEMAZEPAM	capsule
		52.TERAZOSIN	tablet
		53.THIORIDAZINE	tablet (as hydrochloride)
		54.THYROGLOBULIN	tablet
		55.TOCAINIDE	tablet/injectable
		56.TOLBUTAMIDE	tablet
		57.TRIAZOLAM	tablet
		58.TRIFLUOPERAZINE	tablet
		59.VALPROATE	tablet (as disodium salt) / syrup (as valproic acid)
		60.WARFARIN	table (as sodium salt)