

(e) The Department of Health and Mental Hygiene shall:

~~(1) [establish] ESTABLISH AND MAINTAIN a list of drugs for which drug product selection is restricted or prohibited. This formulary shall contain those drugs for which there is evidence of actual or potential bio-inequivalency of therapeutic significance. The formulary may be added to or deleted from as necessary but shall be updated at least once every six months.~~

~~(2)~~ ESTABLISH AND MAINTAIN A DRUG FORMULARY OF EQUIVALENT DRUG PRODUCTS. THE FORMULARY:

(I) SHALL LIST ALL DRUG PRODUCTS THAT THE COMMISSIONER OF FOOD AND DRUG, UNITED STATES FOOD AND DRUG ADMINISTRATION, HAS APPROVED AS SAFE AND EFFECTIVE, AND HAS DETERMINED TO BE THERAPEUTICALLY EQUIVALENT;

(II) SHALL LIST ALL DRUG PRODUCTS THAT WERE NOT SUBJECT TO PREMARKETING APPROVAL FOR SAFETY AND EFFECTIVENESS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, ARE MANUFACTURED BY FIRMS MEETING THE REQUIREMENTS OF THAT ACT, ARE SUBJECT TO PHARMACOPEIAL STANDARDS ADEQUATE TO ASSURE PRODUCT QUALITY, AND HAVE BEEN DETERMINED BY THE COMMISSIONER OF FOOD AND DRUGS TO MEET ANY OTHER REQUIREMENTS NECESSARY TO ASSURE THERAPEUTIC EQUIVALENCE; AND

(III) MAY LIST ADDITIONAL DRUG PRODUCTS THAT ARE DETERMINED BY THE DEPARTMENT TO MEET REQUIREMENTS ADEQUATE TO ASSURE PRODUCT QUALITY AND THERAPEUTIC EQUIVALENCE; AND

~~(3)~~ (2) PROVIDE FOR REVISION OF THE FORMULARIES AS NECESSARY BUT NOT LESS THAN EVERY 6 MONTHS; AND

~~(4)~~ (3) PROVIDE FOR DISTRIBUTION OF THE FORMULARIES AND REVISIONS TO ALL PHARMACIES AND PRESCRIBERS LICENSED IN THIS STATE AND TO OTHER APPROPRIATE INDIVIDUALS.

(F) THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE SHALL:

(1) ASSESS THE NEED FOR PUBLIC EDUCATION REGARDING THE PROVISIONS OF THIS SECTION;

(2) PROVIDE FOR THAT EDUCATION IF APPROPRIATE; AND

(3) MONITOR THE EFFECTS OF THE SECTION PERIODICALLY.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 1979.

Approved May 29, 1979.

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