

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL
No. 1227 Session of
1989

INTRODUCED BY ITKIN, D. W. SNYDER, PISTELLA, HOWLETT, DeWEESE,
KUKOVICH, RYBAK, MICHLOVIC, MERRY, FEE, MORRIS, ROBINSON,
GEIST, TIGUE, GIGLIOTTI, TRELLO, MAIALE, JOHNSON, MELIO,
DeLUCA, WOZNIAK, RITTER, JAROLIN AND VEON, APRIL 19, 1989

REFERRED TO COMMITTEE ON HEALTH AND WELFARE, APRIL 19, 1989

AN ACT

1 Amending the act of November 24, 1976 (P.L.1163, No.259),
2 entitled "An act relating to the prescribing and dispensing
3 of generic equivalent drugs," requiring the department to
4 publish updated formulary lists.

5 The General Assembly of the Commonwealth of Pennsylvania
6 hereby enacts as follows:

7 Section 1. Section 5(a) of the act of November 24, 1976
8 (P.L.1163, No.259), referred to as the Generic Equivalent Drug
9 Law, is amended to read:

10 Section 5. (a) The Department of Health shall have the
11 power and its duty shall be to:

12 (1) Administer and enforce the provisions of this act.

13 (2) Adopt necessary regulations consistent with this act.

14 (3) Publicize the provisions of this act.

15 (4) [Distribute in cooperation with the Pennsylvania Board
16 of Pharmacy periodically an updated formulary of generically
17 equivalent drug products to all pharmacies in the Commonwealth.]
18 The department shall publish and, at least every three months,

update a formulary that lists those substitutions that may be
made under this section. The formulary:

(i) automatically shall list all drug products that the
Commissioner of Food and Drugs of the United States Food and
Drug Administration has:

(A) approved as safe and effective; and

(B) determined to be therapeutically equivalent;

(ii) automatically shall list all drug products that:

(A) were not subject to premarketing approval for safety and
effectiveness under the Federal Food, Drug, and Cosmetic Act (52
Stat. 1040, 21 U.S.C. § 301 et seq.);

(B) are manufactured by firms meeting the requirements of
that act;

(C) are subject to pharmacopoeial standards that are
adequate to assure product quality; and

(D) have been determined by the Commissioner of Food and
Drugs to meet any other requirements necessary to assure
therapeutic equivalence; and

(iii) may list any additional drug products that are
determined by the department to meet requirements that are
adequate to assure product quality and therapeutic equivalence.

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Section 2. This act shall take effect in 60 days.