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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL No. **1111** ^{Session of} 1989

INTRODUCED BY GREENWOOD, DAWIDA, PORTERFIELD, SALVATORE, HELFRICK, LEWIS AND ANDREZESKI, JUNE 26, 1989

AS AMENDED ON THIRD CONSIDERATION, HOUSE OF REPRESENTATIVES, JUNE 30, 1990

AN ACT

1 2 3 4	Amending the act of November 24, 1976 (P.L.1163, No.259), entitled "An act relating to the prescribing and dispensing of generic equivalent drugs," further providing for the addition and deletion of generic drugs.from the formulary.
5	The General Assembly of the Commonwealth of Pennsylvania
б	hereby enacts as follows:
7	Section 1. Section 3(a) of the act of November 24, 1976
8	(P.L.1163, No.259), referred to as the Generic Equivalent Drug
9	Law, amended December 15, 1988 (P.L.1257, No.154), is amended to
10	read :
11	Section 3. (a) Whenever a pharmacist receives a
12	prescription for a brand name drug he shall, unless requested
13	otherwise by the purchaser, substitute a less expensive
14	generically equivalent drug product listed in the formulary of
15	generic and brand name drug products developed by the Department
16	of Health as provided in section 5(b) and (c) unless the
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1	blank shall be imprinted with the words "substitution	
2	permissible" and shall contain one signature line for the	
3	physician's or other authorized prescriber's signature. The	
4	prescriber's signature shall validate the prescription and,	
5	unless the prescriber handwrites "brand necessary" or "brand	
6	medically necessary, " shall designate approval of substitution	
7	of a drug by a pharmacist pursuant to this act. Imprinted	
8	conspicuously on the prescription blanks shall be the words: "In	
9	order for a brand name product to be dispensed, the prescriber	
10	must handwrite 'brand necessary' or 'brand medically necessary'	
11	in the space below." All information printed on the prescription	
12	blank shall be in eight point uppercase print. In the case of an	
13	oral prescription, there will be no substitution if the	
14	prescriber expressly indicates to the pharmacist that the brand	
15	name drug is necessary and substitution is not allowed.	
16	Substitution of a less expensive generically equivalent drug	
17	product shall be contingent on whether the pharmacy has the	
18	brand name or generically equivalent drug in stock.	
19	<u>* * *</u>	
20	Section 2. Section 5 of the act is amended to read:	
21	Section 5. (a) The Department of Health shall have the	
22	power and its duty shall be to:	
23	(1) Administer and enforce the provisions of this act.	
24	(2) Adopt necessary regulations consistent with this act.	
25	(3) Publicize the provisions of this act.	
26	(4) Distribute in cooperation with the Pennsylvania Board of	
27	Pharmacy periodically an updated formulary of generically	
28	equivalent drug products to all pharmacies in the Commonwealth.	
29	(b) The Secretary of Health in cooperation with the	
30	Pennsylvania Drug, Device and Cosmetic Board shall within 180	
19890S1111B2416 - 2 -		

days of the effective date of this act establish a formulary of 1 generically equivalent drugs and the name of their 2 manufacturers. In compiling the list of generic and brand name 3 4 drug products for inclusion in the formulary, the secretary may 5 adopt in whole or in part formularies adopted by the United States Department of Health, Education and Welfare for their 6 maximum allowable cost program for drug reimbursements under 7 8 Title XVIII and Title XIX of the Social Security Act. In the event of an emergency, as determined by the secretary to affect 9 10 the health or safety of the public, the secretary may remove a 11 drug product from the list without public hearings. If the formulary for the maximum allowable cost program is adopted by 12 13 the secretary, formal hearings as required in [the act of June 14 4, 1945 (P.L.1388, No.422), known as the "Administrative Agency 15 Law,"] Title 2 of the Pennsylvania Consolidated Statutes (relating to administrative law and procedure) may be waived 16 otherwise the inclusions of all drugs in the formulary shall be 17 18 in compliance with the provisions of the [Administrative Agency 19 Law] Title 2 of the Pennsylvania Consolidated Statutes. The 20 formulary may be added to or deleted from upon the motion of the 21 secretary or on the petition of any interested party [however]. 22 However, before such addition or deletion the secretary shall 23 [request] receive the advice in writing from the Drug, Device and Cosmetic Board whether a drug should be added or deleted. 24 25 [Such advice shall be rendered to the secretary within a 26 reasonable time. After considering the available facts, the 27 secretary shall make a finding with respect to such drug and may 28 issue a regulation on its substitution for a period of one year. 29 The status of such drugs as well as the formulary shall be 30 reviewed annually by the secretary.]

19890S1111B2416

- 3 -

1	(c) A Pennsylvania Generic Drug Law Formulary Application		
2	shall remain active for one year from the date of its		
3	notarization. The Office of Drugs, Devices and Cosmetics shall		
4	accept applications prior to a manufacturer receiving final		
5	United States Food and Drug Administration (FDA) approval.		
6	<u>Within 14 days of receiving a complete application and</u>		
7	information, the representative of the Office of Drugs, Devices		
8	and Cosmetics shall forward any pertinent clinical information		
9	<u>or bioequivalence studies to a consultant pharmacologist</u>		
10	designated by the Drug, Device and Cosmetic Board for review.		
11	<u>The consultant pharmacologist shall have a total of 60 days to</u>		
12	review any clinical information after he has received all of the		
13	data needed for review from the drug manufacturer. The		
14	consultant pharmacologist shall then make his recommendation in		
15	writing to the Technical Advisory Committee (TAC). After at		
16	least 30 days notice, but no longer than 60 days notice, from		
17	the time the TAC receives the recommendation on a drug from the		
18	pharmacologist, a public hearing shall be held by the TAC, or by		
19	personnel of the department designated by the secretary, to hear		
20	testimony from all parties affected by the possible inclusion of		
21	a generic drug on the drug formulary. Such notice shall be		
22	mailed to every drug manufacturer that is authorized to do		
23	business in this Commonwealth and to all persons who have made a		
24	timely request of the TAC for advance notice of its public		
25	<u>hearings and shall be published in the Pennsylvania Bulletin.</u>		
26	The TAC shall meet quarterly, and at that time shall review the		
27	recommendations of the consultant pharmacologist and the		
28	information provided at the public hearing and make its		
29	recommendation to the Drug, Device and Cosmetic Board within ten		
30	working days after the quarterly meeting. The board shall have		
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19890S1111B2416

- 4 -

1	14 days to make its recommendation to the secretary. Any
2	<u>decision to reject a drug for inclusion on the formulary must be</u>
3	accompanied by a written explanation of the basis for the
4	decision. A manufacturer may not resubmit an application after
5	it has been rejected unless additional information is included
6	which responds to the written explanation of the basis for
7	rejection of the original application. After considering the
8	available facts, the secretary shall make a finding with respect
9	to such drug and shall issue a determination on its substitution
10	for a period of one year, within 14 working days. The date of
11	this determination shall be the date such drug shall be legally
12	substitutable in this Commonwealth. The department shall issue a
13	quarterly formulary update. The status of such drugs as well as
14	the formulary shall be reviewed annually by the secretary.
15	(d) For the purposes of this act, the act of July 31, 1968
16	(P.L.769, No.240), referred to as the Commonwealth Documents
17	Law, the act of October 15, 1980 (P.L.950, No.164), known as the
18	<u>"Commonwealth Attorneys Act," and the act of June 25, 1982</u>
19	(P.L.633, No.181), known as the "Regulatory Review Act," the
20	formulary or any addition or deletion to the formulary shall not
21	be considered a rule or regulation.
22	Section 3. This act shall take effect in 60 days.
23	SECTION 1. THE DEFINITION OF "GENERICALLY EQUIVALENT DRUG" $<-$
24	IN SECTION 2 OF THE ACT OF NOVEMBER 24, 1976 (P.L.1163, NO.259),
25	REFERRED TO AS THE GENERIC EQUIVALENT DRUG LAW, IS AMENDED TO
26	READ:
27	SECTION 2. AS USED IN THIS ACT:
28	* * *
29	"GENERICALLY EQUIVALENT DRUG" MEANS A DRUG PRODUCT [HAVING
30	THE SAME GENERIC NAME, DOSAGE FORM AND LABELED POTENCY, MEETING

- 5 -

STANDARDS OF THE UNITED STATES PHARMACOPOEIA OR NATIONAL 1 2 FORMULARY OR THEIR SUCCESSORS, IF APPLICABLE, AND NOT FOUND IN 3 VIOLATION OF THE REQUIREMENTS OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR THE PENNSYLVANIA DEPARTMENT OF HEALTH.] THAT 4 5 THE COMMISSIONER OF FOOD AND DRUGS OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION HAS APPROVED AS SAFE AND EFFECTIVE AND HAS 6 DETERMINED TO BE THERAPEUTICALLY EQUIVALENT, AS LISTED IN "THE 7 8 APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE 9 EVALUATIONS, " (FOOD AND DRUG ADMINISTRATION "ORANGE BOOK"), 10 PROVIDED, HOWEVER, THAT DRUG PRODUCTS FOUND BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO HAVE A NARROW THERAPEUTIC RANGE 11 12 SHALL NOT BE CONSIDERED GENERICALLY EQUIVALENT FOR THE PURPOSES 13 OF THIS ACT. * * * 14 15 SECTION 2. SECTION 3(A) AND (F) OF THE ACT, AMENDED DECEMBER 16 15, 1988 (P.L.1257, NO.154), ARE AMENDED TO READ: 17 SECTION 3. (A) WHENEVER A PHARMACIST RECEIVES A 18 PRESCRIPTION FOR A BRAND NAME DRUG [HE SHALL, UNLESS REQUESTED

OTHERWISE BY THE PURCHASER, SUBSTITUTE A LESS EXPENSIVE 19 20 GENERICALLY EQUIVALENT DRUG PRODUCT LISTED IN THE FORMULARY OF 21 GENERIC AND BRAND NAME DRUG PRODUCTS DEVELOPED BY THE DEPARTMENT 22 OF HEALTH AS PROVIDED IN SECTION 5(B) UNLESS THE PRESCRIBER 23 INDICATES OTHERWISE.] THE PHARMACIST SHALL SUBSTITUTE A LESS 24 EXPENSIVE GENERICALLY EQUIVALENT DRUG UNLESS REQUESTED OTHERWISE 25 BY THE PURCHASER OR INDICATED OTHERWISE BY THE PRESCRIBER. THE 26 BOTTOM OF EVERY PRESCRIPTION BLANK SHALL BE IMPRINTED WITH THE 27 WORDS "SUBSTITUTION PERMISSIBLE" AND SHALL CONTAIN ONE SIGNATURE 28 LINE FOR THE PHYSICIAN'S OR OTHER AUTHORIZED PRESCRIBER'S 29 SIGNATURE. THE PRESCRIBER'S SIGNATURE SHALL VALIDATE THE 30 PRESCRIPTION AND, UNLESS THE PRESCRIBER HANDWRITES "BRAND 19890S1111B2416 - 6 -

NECESSARY" OR "BRAND MEDICALLY NECESSARY," SHALL DESIGNATE 1 APPROVAL OF SUBSTITUTION OF A DRUG BY A PHARMACIST PURSUANT TO 2 3 THIS ACT. IMPRINTED CONSPICUOUSLY ON THE PRESCRIPTION BLANKS 4 SHALL BE THE WORDS: "IN ORDER FOR A BRAND NAME PRODUCT TO BE 5 DISPENSED, THE PRESCRIBER MUST HANDWRITE 'BRAND NECESSARY' OR 'BRAND MEDICALLY NECESSARY' IN THE SPACE BELOW." ALL INFORMATION 6 7 PRINTED ON THE PRESCRIPTION BLANK SHALL BE IN EIGHT-POINT UPPERCASE PRINT. IN THE CASE OF AN ORAL PRESCRIPTION, THERE WILL 8 9 BE NO SUBSTITUTION IF THE PRESCRIBER EXPRESSLY INDICATES TO THE 10 PHARMACIST THAT THE BRAND NAME DRUG IS NECESSARY AND 11 SUBSTITUTION IS NOT ALLOWED. SUBSTITUTION OF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG [PRODUCT] SHALL BE CONTINGENT ON 12 13 WHETHER THE PHARMACY HAS THE BRAND NAME OR GENERICALLY 14 EQUIVALENT DRUG IN STOCK.

15 * * *

16 (F) NO PHARMACIST SHALL SUBSTITUTE A GENERICALLY EQUIVALENT 17 DRUG PRODUCT FOR A PRESCRIBED BRAND NAME DRUG PRODUCT IF THE 18 BRAND NAME DRUG PRODUCT OR THE GENERIC DRUG TYPE IS NOT INCLUDED 19 IN THE FORMULARY DEVELOPED BY THE DEPARTMENT OF HEALTH IN 20 ACCORDANCE WITH THE PROVISIONS OF SECTION 5(B).] FOR A 21 PRESCRIBED BRAND NAME DRUG UNLESS THE GENERICALLY EQUIVALENT 22 DRUG MEETS THE DEFINITION OF GENERICALLY EQUIVALENT DRUG SET 23 FORTH IN THIS ACT AND THE SECRETARY HAS NOT PROHIBITED THE USE 24 OF THE DRUG IN ACCORDANCE WITH SECTION 5.

25 SECTION 3. SECTIONS 4(B) AND 5 OF THE ACT ARE AMENDED TO 26 READ:

27 SECTION 4. * * *

(B) EVERY PHARMACY SHALL POST IN A CONSPICUOUS PLACE, EASILY
ACCESSIBLE TO THE GENERAL PUBLIC, A LIST OF COMMONLY USED
GENERICALLY EQUIVALENT DRUGS [FROM THE FORMULARY] CONTAINING THE
19890S1111B2416 - 7 -

1 GENERIC NAMES AND BRAND NAMES WHERE APPLICABLE.

2 * * *

3 SECTION 5. (A) THE DEPARTMENT OF HEALTH SHALL HAVE THE 4 POWER AND ITS DUTY SHALL BE TO:

5 (1) ADMINISTER AND ENFORCE THE PROVISIONS OF THIS ACT.

6 (2) ADOPT NECESSARY REGULATIONS CONSISTENT WITH THIS ACT.

7 (3) PUBLICIZE THE PROVISIONS OF THIS ACT.

8 (4) [DISTRIBUTE IN COOPERATION WITH THE PENNSYLVANIA BOARD 9 OF PHARMACY PERIODICALLY AN UPDATED FORMULARY OF GENERICALLY 10 EQUIVALENT DRUG PRODUCTS TO ALL PHARMACIES IN THE COMMONWEALTH.] 11 PUBLISH BY NOTICE IN THE PENNSYLVANIA BULLETIN THE ADDITION OR 12 DELETION OF GENERICALLY EQUIVALENT DRUGS AND ANY DETERMINATION 13 BY THE SECRETARY TO NOT RECOGNIZE A GENERICALLY EQUIVALENT DRUG 14 IN ACCORDANCE WITH SECTION 5(B). THE DEPARTMENT SHALL ALSO 15 PROVIDE NOTICE THAT A COMPLETE LIST OF GENERICALLY EQUIVALENT 16 DRUGS MAY BE OBTAINED FROM THE UNITED STATES FOOD AND DRUG 17 ADMINISTRATION. THIS NOTICE SHALL BE PUBLISHED AT LEAST EVERY 18 THREE MONTHS.

(B) THE SECRETARY OF HEALTH IN COOPERATION WITH THE 19 20 PENNSYLVANIA DRUG, DEVICE AND COSMETIC BOARD SHALL WITHIN 180 21 DAYS OF THE EFFECTIVE DATE OF THIS ACT ESTABLISH A FORMULARY OF 22 GENERICALLY EQUIVALENT DRUGS AND THE NAME OF THEIR 23 MANUFACTURERS. IN COMPILING THE LIST OF GENERIC AND BRAND NAME 24 DRUG PRODUCTS FOR INCLUSION IN THE FORMULARY, THE SECRETARY MAY 25 ADOPT IN WHOLE OR IN PART FORMULARIES ADOPTED BY THE UNITED 26 STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE FOR THEIR 27 MAXIMUM ALLOWABLE COST PROGRAM FOR DRUG REIMBURSEMENTS UNDER 28 TITLE XVIII AND TITLE XIX OF THE SOCIAL SECURITY ACT. IN THE 29 EVENT OF AN EMERGENCY, AS DETERMINED BY THE SECRETARY TO AFFECT 30 THE HEALTH OR SAFETY OF THE PUBLIC, THE SECRETARY MAY REMOVE A - 8 -19890S1111B2416

1 DRUG PRODUCT FROM THE LIST WITHOUT PUBLIC HEARINGS. IF THE 2 FORMULARY FOR THE MAXIMUM ALLOWABLE COST PROGRAM IS ADOPTED BY 3 THE SECRETARY, FORMAL HEARINGS AS REQUIRED IN THE ACT OF JUNE 4, 4 1945 (P.L.1388, NO.422), KNOWN AS THE "ADMINISTRATIVE AGENCY 5 LAW," MAY BE WAIVED OTHERWISE THE INCLUSIONS OF ALL DRUGS IN THE FORMULARY SHALL BE IN COMPLIANCE WITH THE PROVISIONS OF THE 6 ADMINISTRATIVE AGENCY LAW. THE FORMULARY MAY BE ADDED TO OR 7 DELETED FROM UPON THE MOTION OF THE SECRETARY OR ON THE PETITION 8 9 OF ANY INTERESTED PARTY HOWEVER BEFORE SUCH ADDITION OR DELETION 10 THE SECRETARY SHALL REQUEST THE ADVICE IN WRITING FROM THE DRUG, 11 DEVICE AND COSMETIC BOARD WHETHER A DRUG SHOULD BE ADDED OR DELETED. SUCH ADVICE SHALL BE RENDERED TO THE SECRETARY WITHIN A 12 13 REASONABLE TIME. AFTER CONSIDERING THE AVAILABLE FACTS, THE 14 SECRETARY SHALL MAKE A FINDING WITH RESPECT TO SUCH DRUG AND MAY 15 ISSUE A REGULATION ON ITS SUBSTITUTION FOR A PERIOD OF ONE YEAR. 16 THE STATUS OF SUCH DRUGS AS WELL AS THE FORMULARY SHALL BE 17 REVIEWED ANNUALLY BY THE SECRETARY.] THE SECRETARY, WITH THE 18 ADVICE OF THE PENNSYLVANIA DRUG, DEVICE AND COSMETIC BOARD, MAY 19 DETERMINE THAT A DRUG SHALL NOT BE RECOGNIZED AS A GENERICALLY 20 EQUIVALENT DRUG FOR PURPOSES OF SUBSTITUTION IN PENNSYLVANIA AND 21 THE TIME AFTER WHICH RECOGNITION SHALL BE RESTORED. 22 (C) WHENEVER THE UNITED STATES FOOD AND DRUG ADMINISTRATION 23 HAS DETERMINED A DRUG PRODUCT AS HAVING A NARROW THERAPEUTIC 24 RANGE, THE MANUFACTURER MAY SUBMIT AN APPLICATION FOR REVIEW OF 25 GENERIC EQUIVALENCE WITH THE OFFICE OF DRUGS, DEVICES AND 26 COSMETICS. WITHIN 14 DAYS OF RECEIVING A COMPLETE APPLICATION 27 AND INFORMATION, THE REPRESENTATIVE OF THE OFFICE OF DRUGS, 28 DEVICES AND COSMETICS SHALL FORWARD ANY PERTINENT CLINICAL 29 INFORMATION OR BIOEQUIVALENCE STUDIES TO A CONSULTANT 30 PHARMACOLOGIST DESIGNATED BY THE PENNSYLVANIA DRUG, DEVICE AND

19890S1111B2416

- 9 -

1 COSMETIC BOARD FOR REVIEW. THE CONSULTANT PHARMACOLOGIST SHALL 2 HAVE A TOTAL OF 60 DAYS TO REVIEW ANY CLINICAL INFORMATION AFTER 3 HE HAS RECEIVED ALL OF THE DATA NEEDED FOR REVIEW FROM THE DRUG 4 MANUFACTURER. THE CONSULTANT PHARMACOLOGIST SHALL THEN MAKE HIS 5 RECOMMENDATION IN WRITING TO THE TECHNICAL ADVISORY COMMITTEE (TAC). AFTER AT LEAST 30 DAYS NOTICE, BUT NO LONGER THAN 60 DAYS 6 7 NOTICE, FROM THE TIME THE TAC RECEIVES THE RECOMMENDATION ON A 8 DRUG FROM THE PHARMACOLOGIST, A PUBLIC HEARING SHALL BE HELD BY 9 THE TAC, OR BY PERSONNEL OF THE DEPARTMENT DESIGNATED BY THE 10 SECRETARY, TO HEAR TESTIMONY FROM ALL PARTIES AFFECTED BY THE 11 POSSIBLE INCLUSION OF SUCH A DRUG AS A GENERICALLY EQUIVALENT DRUG FOR PURPOSES OF SUBSTITUTION IN PENNSYLVANIA. SUCH NOTICE 12 13 SHALL BE MAILED TO EVERY DRUG MANUFACTURER THAT IS AUTHORIZED TO 14 DO BUSINESS IN THIS COMMONWEALTH AND TO ALL PERSONS WHO HAVE 15 MADE A TIMELY REQUEST OF THE TAC FOR ADVANCE NOTICE OF ITS 16 PUBLIC HEARINGS AND SHALL BE PUBLISHED IN THE PENNSYLVANIA BULLETIN. THE TAC SHALL MEET QUARTERLY, AND AT THAT TIME SHALL 17 18 REVIEW THE RECOMMENDATIONS OF THE CONSULTANT PHARMACOLOGIST AND 19 THE INFORMATION PROVIDED AT THE PUBLIC HEARING AND MAKE ITS 20 RECOMMENDATION TO THE DRUG, DEVICE AND COSMETIC BOARD WITHIN TEN 21 WORKING DAYS AFTER THE QUARTERLY MEETING. THE BOARD SHALL HAVE 22 14 DAYS TO MAKE ITS RECOMMENDATION TO THE SECRETARY. ANY 23 DECISION TO REJECT OR TO RECOGNIZE SUCH A DRUG AS GENERICALLY 24 EQUIVALENT FOR PURPOSES OF SUBSTITUTION IN PENNSYLVANIA MUST BE 25 ACCOMPANIED BY A WRITTEN EXPLANATION OF THE BASIS FOR THE 26 DECISION. A MANUFACTURER MAY NOT RESUBMIT AN APPLICATION AFTER 27 IT HAS BEEN REJECTED UNLESS ADDITIONAL INFORMATION IS INCLUDED 28 WHICH RESPONDS TO THE WRITTEN EXPLANATION OF THE BASIS FOR 29 REJECTION OF THE ORIGINAL APPLICATION. AFTER CONSIDERING THE 30 AVAILABLE FACTS, THE SECRETARY SHALL MAKE A FINDING WITH RESPECT 19890S1111B2416 - 10 -

1 TO SUCH DRUG AND SHALL ISSUE A DETERMINATION ON ITS SUBSTITUTION 2 FOR A PERIOD OF ONE YEAR, WITHIN 14 WORKING DAYS. THE DATE OF 3 THIS DETERMINATION SHALL BE THE DATE SUCH DRUG SHALL BE LEGALLY 4 SUBSTITUTABLE IN THIS COMMONWEALTH. THE DEPARTMENT SHALL ISSUE A 5 QUARTERLY UPDATE. THE STATUS OF SUCH DRUGS SHALL BE REVIEWED 6 ANNUALLY BY THE SECRETARY. 7 (D) ANY DRUG PRODUCT, HAVING BEEN PREVIOUSLY INCLUDED IN THE 8 PENNSYLVANIA GENERIC DRUG FORMULARY, WHICH THE UNITED STATES 9 FOOD AND DRUG ADMINISTRATION HAS DETERMINED AS HAVING A NARROW 10 THERAPEUTIC RANGE SHALL BE CONSIDERED GENERICALLY EQUIVALENT FOR 11 THE PURPOSES OF THIS ACT UNLESS THE SECRETARY, WITH THE ADVICE 12 OF THE PENNSYLVANIA DRUG, DEVICE AND COSMETIC BOARD, MAKES AN 13 INDEPENDENT DETERMINATION THAT SUCH A PRODUCT IS NOT GENERICALLY 14 EQUIVALENT IN ACCORDANCE WITH THE PROVISIONS OF SUBSECTION (C). 15 SECTION 4. THIS ACT SHALL TAKE EFFECT IN 60 DAYS.