

AMENDMENTS TO SENATE BILL NO. 405

Sponsor:

Printer's No. 401

1 Amend Bill, page 1, line 18, by inserting after "262(k)"
2 (relating to regulation of biological products) or approved
3 based on an application filed under 21 U.S.C. § 355(b)(2)
4 (relating to new drugs) that is highly similar to the prescribed
5 biological product

6 Amend Bill, page 2, lines 1 through 3, by striking out "means
7 a biosimilar product" in line 1 and all of lines 2 and 3 and
8 inserting

9 means a biosimilar that the United States Food and Drug
10 Administration has determined satisfies the standards set forth
11 in 42 U.S.C. § 262(k)(4) (relating to regulation of biological
12 products), the Reference Product for such biosimilar as defined
13 in 42 U.S.C. § 262(i)(4), or with respect to a biosimilar filed
14 under 21 U.S.C. § 355(b)(2) (relating to new drugs), a
15 biosimilar determined by the United States Food and Drug
16 Administration to be therapeutically equivalent to the
17 prescribed brand name biological product.

18 Amend Bill, page 2, line 12, by striking out "for the
19 indicated use." and inserting a semicolon

20 Amend Bill, page 2, line 14, by striking out the period after
21 "prohibited" and inserting a semicolon

22 Amend Bill, page 2, lines 15 and 16, by striking out
23 "provides written" in line 15 and all of line 16 and inserting
24 receives notification of such substitution in the same
25 manner provided in subsection (b);

26 Amend Bill, page 2, lines 17 and 18, by striking out "in
27 writing and as" in line 17 and all of line 18 and inserting
28 either verbally, in writing, or by facsimile, e-mail or other

1 electronic transmission and as soon as practicable but no later
2 than 72 hours after dispensing, except that such notification
3 shall not be required for a prescription refill when the
4 refilled biological product is the same as the product last
5 dispensed by the pharmacist; and

6 Amend Bill, page 2, line 19, by inserting after "written"
7 or electronic

8 Amend Bill, page 2, line 20, by striking out "five" and
9 inserting

10 two

11 Amend Bill, page 2, by inserting between lines 21 and 22

12 (a.2) Subsection (a.1) shall not apply to a biological
13 product which may be dispensed without a prescription.