

HB2531



100TH GENERAL ASSEMBLY

State of Illinois

2017 and 2018

HB2531

by Rep. Norine K. Hammond

SYNOPSIS AS INTRODUCED:

410 ILCS 620/3.14

from Ch. 56 1/2, par. 503.14

Amends the Illinois Food, Drug and Cosmetic Act. Deletes provisions requiring manufacturers to provide the Director of Public Health with a notification containing product technical bioequivalence information no later than 60 days prior to specified generic drug product substitution. Effective immediately.

LRB100 08313 MJP 18420 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

1 AN ACT concerning health.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 5. The Illinois Food, Drug and Cosmetic Act is
5 amended by changing Section 3.14 as follows:

6 (410 ILCS 620/3.14) (from Ch. 56 1/2, par. 503.14)

7 Sec. 3.14. Dispensing or causing to be dispensed a
8 different drug in place of the drug or brand of drug ordered or
9 prescribed without the express permission of the person
10 ordering or prescribing. Except as set forth in Section 26 of
11 the Pharmacy Practice Act, this Section does not prohibit the
12 interchange of different brands of the same generically
13 equivalent drug product, when the drug products are not
14 required to bear the legend "Caution: Federal law prohibits
15 dispensing without prescription", provided that the same
16 dosage form is dispensed and there is no greater than 1%
17 variance in the stated amount of each active ingredient of the
18 drug products. A generic drug determined to be therapeutically
19 equivalent by the United States Food and Drug Administration
20 (FDA) shall be available for substitution in Illinois in
21 accordance with this Act and the Pharmacy Practice Act,
22 ~~provided that each manufacturer submits to the Director of the~~
23 ~~Department of Public Health a notification containing product~~

1 ~~technical bioequivalence information as a prerequisite to~~
2 ~~product substitution when they have completed all required~~
3 ~~testing to support FDA product approval and, in any event, the~~
4 ~~information shall be submitted no later than 60 days prior to~~
5 ~~product substitution in the State.~~

6 (Source: P.A. 94-936, eff. 6-26-06; 95-689, eff. 10-29-07.)

7 Section 99. Effective date. This Act takes effect upon
8 becoming law.