



General Assembly

January Session, 2021

Substitute Bill No. 262



**AN ACT REQUIRING MANUFACTURERS OF BRAND NAME
PRESCRIPTION DRUGS TO PROVIDE SAMPLES OF SUCH DRUGS
TO MANUFACTURERS OF GENERIC PRESCRIPTION DRUGS.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2021*) (a) As used in this section:
2 (1) "Eligible product developer" means a person who seeks to develop
3 an application for the approval of a drug under subsections (b) and (j)
4 of Section 505 of the federal Food, Drug and Cosmetic Act or the
5 licensing of a biological product under Section 351 of the federal Public
6 Health Service Act, and (2) "wholesale acquisition cost" means the
7 manufacturer's list price for a brand-name drug or a generic drug per
8 person, year or course of treatment, when sold to wholesalers or direct
9 purchasers in the United States, not including discounts or rebates, for
10 the most recent month for which information is available.

11 (b) A manufacturer or wholesaler registered under chapter 417 of the
12 general statutes shall make a drug manufactured or developed by such
13 manufacturer or wholesaler and distributed in this state available for
14 sale in this state to an eligible product developer for purposes of
15 conducting testing required to support an application by such eligible
16 product developer for approval of a drug under subsections (b) and (j)
17 of Section 505 of the federal Food, Drug and Cosmetic Act, or the
18 licensing of a biological product under Section 351 of the federal Public
19 Health Service Act. Such manufacturer or wholesaler shall make the

20 drug available for sale to such eligible product developer at a price not
21 greater than the wholesale acquisition cost of the drug and without any
22 restriction that would block or delay the eligible product developer's
23 application in a manner inconsistent with Section 505-1(f)(8) of the
24 federal Food, Drug and Cosmetic Act.

25 (c) An eligible product developer that receives a drug at a price not
26 greater than the wholesale acquisition cost for such drug pursuant to
27 this section shall charge consumers in this state the same price or less
28 for the drug manufactured by such eligible product developer.

29 (d) A manufacturer or wholesaler registered under chapter 417 of the
30 general statutes shall not be liable for injuries alleged to have been
31 caused by the failure of the eligible product developer to include
32 adequate safety warnings on a product's label or by a defect in the
33 product's design if (1) such manufacturer or wholesaler has made the
34 product distributed in this state available to an eligible product
35 developer in accordance with the provisions of this section, and (2) the
36 product was not manufactured or sold by such manufacturer or
37 wholesaler.

38 (e) A violation of any of the provisions of subsection (b) or (c) of this
39 section shall be deemed an unfair or deceptive trade practice under
40 subsection (a) of section 42-110b of the general statutes.

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2021	New section

GL *Joint Favorable Subst. -LCO*

JUD *Joint Favorable*

APP *Joint Favorable*