

110TH CONGRESS
1ST SESSION

S. 438

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs.

IN THE SENATE OF THE UNITED STATES

JANUARY 30, 2007

Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. KOHL, and Mr. LEAHY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fair Prescription Drug
5 Competition Act”.

6 **SEC. 2. PROHIBITION OF AUTHORIZED GENERICS.**

7 Section 505 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 355) is amended by adding at the end the
9 following:

1 “(o) PROHIBITION OF AUTHORIZED GENERIC
2 DRUGS.—

3 “(1) IN GENERAL.—Notwithstanding any other
4 provision of this Act, no holder of a new drug appli-
5 cation approved under subsection (c) shall manufac-
6 ture, market, sell, or distribute an authorized ge-
7 neric drug, direct or indirectly, or authorize any
8 other person to manufacture, market, sell, or dis-
9 tribute an authorized generic drug.

10 “(2) AUTHORIZED GENERIC DRUG.—For pur-
11 poses of this subsection, the term ‘authorized generic
12 drug’—

13 “(A) means any version of a listed drug
14 (as such term is used in subsection (j)) that the
15 holder of the new drug application approved
16 under subsection (c) for that listed drug seeks
17 to commence marketing, selling, or distributing,
18 directly or indirectly, after receipt of a notice
19 sent pursuant to subsection (j)(2)(B) with re-
20 spect to that listed drug; and

21 “(B) does not include any drug to be mar-
22 keted, sold, or distributed—

23 “(i) by an entity eligible for exclu-
24 sivity with respect to such drug under sub-
25 section (j)(5)(B)(iv); or

1 “(ii) after expiration or forfeiture of
2 any exclusivity with respect to such drug
3 under such subsection (j)(5)(B)(iv).”.

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