

109TH CONGRESS  
2D SESSION

# S. 3695

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

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IN THE SENATE OF THE UNITED STATES

JULY 19, 2006

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

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## 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. PROHIBITION OF AUTHORIZED GENERICS.**

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

7       “(o) PROHIBITION OF AUTHORIZED GENERIC  
8       DRUGS.—

9               “(1) IN GENERAL.—Notwithstanding any other  
10       provision of this Act, no holder of a new drug appli-

1 cation approved under subsection (c) shall manufac-  
2 ture, market, sell, or distribute an authorized ge-  
3 neric drug, direct or indirectly, or authorize any  
4 other person to manufacture, market, sell, or dis-  
5 tribute an authorized generic drug.

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

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

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

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

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

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