

103^D CONGRESS
1ST SESSION

S. 1734

To amend the Federal Food, Drug, and Cosmetic Act to expand the provisions relating to market exclusivity.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 20 (legislative day, NOVEMBER 2), 1993

Mr. SIMON (for himself, Mr. HATCH, and Ms. MOSELEY-BRAUN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to expand the provisions relating to market exclusivity.

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 “Market Exclusivity Act
5 of 1993”.

6 **SEC. 2. MARKET EXCLUSIVITY.**

7 Section 505(j)(4)(D) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 355(j)(4)(D)) is amended by
9 adding at the end the following new clause:

10 “(vi) If—

1 “(I) an application (other than an abbreviated
2 new drug application) was submitted under sub-
3 section (b) for a drug;

4 “(II) no active ingredient of the drug (including
5 an ester or salt of the active ingredient) has been
6 approved in any other application under subsection
7 (b);

8 “(III) the application was filed before Septem-
9 ber 1, 1982;

10 “(IV) the application was under regulatory re-
11 view for a regulatory review period (as defined in
12 section 156(g) of title 35, United States Code) for
13 at least 78 months; and

14 “(V) the application was approved October 29,
15 1992,

16 no application may be submitted under this subsection
17 that refers to the drug for which the subsection (b) appli-
18 cation was submitted before the expiration of 5 years from
19 the date of the approval of the subsection (b) application,
20 and no application submitted under this subsection that
21 refers to such drug may be approved before the expiration
22 of 5 years from the date of approval of the subsection (b)
23 application plus the amount by which the regulatory re-
24 view period exceeds 84 months, except that the period for

1 such amount of additional market exclusivity shall not ex-
2 ceed 24 months.”.

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