

103^D CONGRESS
1ST SESSION

H. R. 3552

Respecting market exclusivity for certain drugs.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 19, 1993

Mrs. COLLINS of Illinois introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

Respecting market exclusivity for certain drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That section 505(j)(4)(D)(ii) of the Federal Food, Drug,
4 and Cosmetic Act is amended by adding the following: “If
5 an application (other than an abbreviated new drug appli-
6 cation) submitted under subsection (b) for a drug, no ac-
7 tive ingredient (including an ester or salt of the active in-
8 gredient) of which has been approved in any other applica-
9 tion under subsection (b), was filed before September 1,
10 1982, was under regulatory review (as the regulatory re-
11 view period is defined in section 156(g) of title 35, United
12 States Code) for at least 78 months and was approved

1 October 29, 1992, no application may be submitted under
2 this subsection which refers to the drug for which the sub-
3 section (b) application was submitted before the expiration
4 of 5 years from the date of the approval of the subsection
5 (b) application and no such application can be approved
6 before the expiration of 5 years from the date of the ap-
7 proval of the subsection (b) application plus the amount
8 by which the regulatory review period exceeds 84 months,
9 except that the period of additional market exclusivity may
10 not exceed 24 months.”.

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