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112TH CONGRESS
1ST SESSION

H. R. 741

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2011

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROHIBITION OF AUTHORIZED GENERICS.

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

''(w) PROHIBITION OF AUTHORIZED GENERIC DRUGS.—

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

cation approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, direct or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.

''(2) AUTHORIZED GENERIC DRUG.—For purposes of this subsection, the term 'authorized generic drug'—

''(A) means any version of a listed drug (as such term is used in subsection (j)) that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice sent pursuant to subsection (j)(2)(B) with respect to that listed drug; and

''(B) does not include any drug to be marketed, sold, or distributed—

''(i) by an entity eligible for exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

''(ii) after expiration or forfeiture of any exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).''.

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