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

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 manufac-
ture, market, sell, or distribute an authorized ge-
eric drug, direct or indirectly, or authorize any
other person to manufacture, market, sell, or dis-
tribute an authorized generic drug.

“(2) AUTHORIZED GENERIC DRUG.—For pur-
poses 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 re-
spect to that listed drug; and

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

“(i) by an entity eligible for exclu-
sivity with respect to such drug under sub-
section (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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