

112TH CONGRESS
1ST SESSION

H. R. 3230

To direct the Food and Drug Administration, with respect to devices, to enter into agreements with certain countries regarding methods and approaches to harmonizing certain regulatory requirements.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 14, 2011

Mrs. MCMORRIS RODGERS (for herself, Mr. LANCE, Mr. GUTHRIE, Mrs. BLACKBURN, Mr. PAULSEN, Mr. BASS of New Hampshire, Mr. LATTA, and Mr. SHIMKUS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To direct the Food and Drug Administration, with respect to devices, to enter into agreements with certain countries regarding methods and approaches to harmonizing certain regulatory requirements.

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 “Keeping America Com-
5 petitive Through Harmonization Act of 2011”.

1 **SEC. 2. HARMONIZATION OF DEVICE PREMARKET REVIEW,**
2 **INSPECTION, AND LABELING SYMBOLS; RE-**
3 **PORT.**

4 (a) IN GENERAL.—Paragraph (4) of section 803(c)
5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 383(c)) is amended to read as follows:

7 “(4) With respect to devices, the Secretary shall, to
8 the maximum extent practicable, enter into agreements
9 with those countries identified in clauses (i) and (ii) of
10 section 802(b)(1)(A) regarding methods and approaches
11 to harmonizing regulatory requirements for premarket re-
12 view, inspections, and common international labeling sym-
13 bols.”.

14 (b) REPORT.—Not later than 3 years after the date
15 of enactment of this Act, the Secretary of Health and
16 Human Services shall submit to the Committee on Health,
17 Education, Labor, and Pensions of the Senate and the
18 Committee on Energy and Commerce of the House of
19 Representatives, a report listing the agreements entered
20 into under section 803(c)(4) of the Federal Food, Drug,
21 and Cosmetic Act (as amended by subsection (a)) and
22 itemizing the methods and approaches that have been har-
23 monized pursuant to such section.

○