

114TH CONGRESS
1ST SESSION

H. R. 2433

To amend the Federal Food, Drug, and Cosmetic Act with respect to
enhancing combination products review.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. BILIRAKIS 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 with
respect to enhancing combination products review.

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. ENHANCING COMBINATION PRODUCTS RE-**
4 **VIEW.**

5 Section 503(g)(4)(C) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by
7 adding at the end the following new clause:

8 “(iii) Not later than 18 months after the date
9 of the enactment of the 21st Century Cures Act, the
10 Secretary shall issue final guidance that describes

1 the responsibilities of each agency center regarding
2 its review of combination products. The Secretary
3 shall, after soliciting public comment, review and up-
4 date the guidance periodically.”.

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