AMENDMENT TO H.R. 5668

OFFERED BY M__. _____

Page 2, line 17, through page 3, line 3, amend subparagraph (C) to read as follows:

''(C) for which—

''(i)(I) there is new scientific evidence available pertaining to the existing conditions of use that is not reflected in the labeling;

''(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or

''(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and

''(ii) updating the labeling would benefit the public health.

Page 3, line 11, strike ''reference drug'' insert ''reference listed drug''.

Page 7, lines 3 through 6, strike ''and meet the standards under section 505 for adding or modifying in-

formation or providing supplemental information to such labeling''.

Page 7, line 24, strike ''a reference drug'' and insert ''its reference listed drug''.

Page 8, after line 11, insert the following new paragraph:

''(3) SELECTION OF DRUGS.—Nothing in this section shall be construed to give the Secretary the authority to identify a drug as a covered drug or select a drug label for updating solely based on the availability of new safety information.

''(4) MAINTENANCE OF LABELING.—Nothing in this section shall be construed to affect the responsibility of the holder of an approved application under section 505(j) to maintain its labeling in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 314.97 of title 21, Code of Federal Regulations (or any successor regulations).

Page 9, strike lines 5 through 7, and insert ''Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that—''.

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