AMENDMENT TO H.R. 965

OFFERED BY MR. WELCH OF VERMONT

Page 8, lines 14 through 24, amend subparagraph (B) to read as follows:

(B) does not include any drug or biological product that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless—

(i) the drug or biological product has been on such shortage list continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product in the definition of the term ''covered product'' for purposes of this section would likely contribute to alleviating or preventing a shortage.

Page 17, line 7, strike ''other''.

Page 20, lines 19 and 20, strike ''approved risk evaluation and mitigation strategies'' and insert ''aspects of the elements to assure safe use''.

Page 21, after line 17, insert the following (and make such conforming changes as may be necessary):

(3) in subsection (i), by adding at the end the following:

''(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug.''.