AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 3433

OFFERED BY M__. _____

Page 11, before line 12, insert the following (and make such conforming changes as may be necessary):

(a) ELIGIBLE HUMAN DRUG APPLICATIONS.—

(1) DEFINITION.—Section 529(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(a)) is amended—

(A) by redesignating paragraphs (1) through (4) as paragraphs (2) through (5), respectively; and

(B) by inserting before paragraph (2), as redesignated, the following:

''(1) ELIGIBLE SINGLE HUMAN DRUG APPLICATION.—The term 'eligible single human drug application' means a human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act for a drug that—

''(A) is for the prevention or treatment of a rare disease or condition (as defined in section 526(a)(2)); or

''(B) is not known to have the same mechanism of action as any previously approved drug for the same disease or condition.''.

(2) CONFORMING CHANGE.—Section 529(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(a)(2)) is amended by striking ''a single human drug application'' and inserting ''an eligible single human drug application''.

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