

PAUL
 AMENDMENT NO. 4 Calendar No. _____

Purpose: To provide additional incentives for the creation of new therapeutic combination drugs consisting of previously approved active ingredients.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

(no.) _____

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Referred to the Committee on _____ and
 ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

- 1 At the end of title IX, insert the following:
- 2 **SEC. 907. INCENTIVES TO CREATE NEW THERAPEUTIC**
- 3 **COMBINATION DRUGS.**
- 4 Section 505 (21 U.S.C. 355) is amended—
- 5 (1) in subsection (j)(5)(F)(iii), by inserting be-
- 6 fore the period at the end “, except that in the case
- 7 of an application submitted under subsection (b) for
- 8 a drug which contains a combination of active ingre-
- 9 dients of which no such combination of active ingre-
- 10 dients (including any esters or salts of any active in-

1 ingredients) has been approved in any other applica-
2 tion under subsection (b) and which application con-
3 tains new clinical investigations (other than bio-
4 availability studies) essential to the approval of the
5 application and conducted or sponsored by the appli-
6 cant, no application submitted under this subsection
7 for a drug which contains the same combination of
8 active ingredients (including any esters or salts of
9 any active ingredients) may be submitted under this
10 subsection which refers to the drug for which the ap-
11 plication under subsection (b) was submitted before
12 the expiration of 3 years from the date of approval
13 of the application under subsection (b)”; and

14 (2) in subsection (c)(3)(E)(iii), by inserting be-
15 fore the period at the end “, except that in the case
16 of an application submitted under subsection (b) for
17 a drug which contains a combination of active ingre-
18 dients of which no such combination of active ingre-
19 dients (including any esters or salts of any active in-
20 gredients) has been approved in any other applica-
21 tion under subsection (b) and which application con-
22 tains reports of new clinical investigations (other
23 than bioavailability studies) essential to the approval
24 of the drug and conducted or sponsored by the ap-
25 plicant, no application submitted under subsection

1 (b) for a drug which contains the same combination
2 of active ingredients (including any esters or salts
3 of any active ingredients) may be submitted under
4 this subsection (b) which refers to the drug for
5 which the application under subsection (b) was sub-
6 mitted before the expiration of 3 years from the date
7 of approval of the application under subsection (b)".