

## MANAGER'S AMENDMENT

OFFERED BY M\_\_\_\_. \_\_\_\_\_

**[Page and line numbers refer to Committee Print of H.R. 2430, as forwarded by the Subcommittee on Health]**

Page 83, line 17, strike “knowingly selling” and insert “knowingly making, selling”.

Page 94, line 8, insert “(A)” before “In this subsection”.

Page 94, line 10, strike “(A)” and insert “(i)” and move the margins two ems to the right.

Page 94, line 18, strike “(B)” and insert “(ii)” and move the margins two ems to the right.

Page 94, line 21, strike “(C)” and insert “(iii)” and move the margins two ems to the right.

Page 94, line 25, strike “(D)” and insert “(iv)” and move the margins two ems to the right.

Page 95, line 3, strike “(E)” and insert “(v)” and move the margins two ems to the right.

Page 95, after line 7, insert the following new subparagraph:

1           “(B) Such term does not include a per-  
2           sonal sound amplification product intended to  
3           amplify sound for non-hearing impaired con-  
4           sumers in situations including, hunting and  
5           bird-watching.”.

Page 96, strike lines 11 through 16 and insert the following new subparagraph:

6           (C) include requirements for appropriate  
7           labeling of the over-the-counter hearing aid, in-  
8           cluding requirements that such labeling include  
9           a conspicuous statement that the device is only  
10          intended for adults over the age of 18, informa-  
11          tion on how consumers may report adverse  
12          events, information on any contraindications,  
13          conditions, or symptoms of medically treatable  
14          causes of hearing loss, and advisements to con-  
15          sult promptly with a licensed physician; and

Page 97, line 10, strike “applicable” and insert “re-  
lated”.

Page 97, after line 23, add at the end the following  
paragraph:

16           (5) NO EFFECT ON PRIVATE REMEDIES.—Noth-  
17          ing in this section shall be construed to modify or  
18          otherwise affect the ability of any person to exercise

1 a private right of action under any State or Federal  
2 product liability, tort, warranty, contract, or con-  
3 sumer protection law.

Page 98, after line 11, add at the end the following  
new subsection:

4 (d) REPORT.—Not later than 2 years after the date  
5 on which the final regulations described in subsection  
6 (b)(1) are issued, the Secretary of Health and Human  
7 Services shall submit to Congress a report analyzing any  
8 adverse events relating to over-the-counter hearing aids  
9 (as defined in subsection (p)(1) of section 520 of the Fed-  
10 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360j)).

Page 99, line 9, after “designation as a competitive  
generic therapy” insert “under this section”.Page 100,  
line 6, strike “nonclinical and clinical”.

Page 99, line 23, strike “as appropriate” and insert  
“as requested by the sponsor”.

Page 100, line 6, strike “nonclinical and clinical”.

Page 100, lines 10 and 11, strike “cross-discipli-  
nary” and insert “coordinated”.

Page 100, line 25, strike “means” and insert  
“means, with respect to a product,”.

Beginning on page 104, line 1, amend sections 703, 704, and 705 of the bill to read as follows:

1 **SEC. 703. INCENTIVIZING COMPETITIVE GENERIC THERAPY**  
2 **DEVELOPMENT.**

3 Section 505(j)(5) of the Federal Food, Drug, and  
4 Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

5 (1) in subparagraph (B), by adding at the end  
6 the following:

7 “(v) 180-DAY EXCLUSIVITY PERIOD FOR COM-  
8 PETITIVE GENERIC THERAPIES.—

9 “(I) EFFECTIVENESS OF APPLICATION.—

10 Subject to subparagraph (D)(iv), if the applica-  
11 tion is for a drug that is the same as a competi-  
12 tive generic therapy for which any first ap-  
13 proved applicant has commenced commercial  
14 marketing, the application shall be made effec-  
15 tive on the date that is 180 days after the date  
16 of the first commercial marketing of the com-  
17 petitive generic therapy (including the commer-  
18 cial marketing of the listed drug) by any first  
19 approved applicant.

20 “(II) LIMITATION.—The exclusivity period  
21 under subclause (I) shall not apply with respect  
22 to a competitive generic therapy has previously

1 received an exclusivity period under subclause  
2 (I).

3 “(III) DEFINITIONS.—In this clause and  
4 subparagraph (D)(iv):

5 “(aa) The term ‘competitive generic  
6 therapy’ means a drug—

7 “(AA) that is designated as a  
8 competitive generic therapy under sec-  
9 tion 506H; and

10 “(BB) for which there are no un-  
11 expired patents or blocking  
12 exclusivities on the list of products de-  
13 scribed in section 505(j)(7)(A) at the  
14 time of approval.

15 “(bb) The term ‘first approved appli-  
16 cant’ means any applicant that has sub-  
17 mitted an application that—

18 “(AA) is for a competitive ge-  
19 neric therapy that is approved on the  
20 first day on which any application for  
21 such competitive generic therapy is  
22 approved;

23 “(BB) is not eligible for a 180-  
24 day exclusivity period under clause  
25 (iv) for the drug that is the subject of

1 the application for the competitive ge-  
2 neric therapy; and

3 “(CC) is not for a drug for which  
4 all drug versions have forfeited eligi-  
5 bility for a 180-day exclusivity period  
6 under clause (iv) pursuant to subpara-  
7 graph (D).”; and

8 (2) in subparagraph (D), by adding at the end  
9 the following:

10 “(iv) SPECIAL FORFEITURE RULE FOR  
11 COMPETITIVE GENERIC THERAPY.—The  
12 180-day exclusivity period described in  
13 subparagraph (B)(v) shall be forfeited by a  
14 first approved applicant if the applicant  
15 fails to market the competitive generic  
16 therapy within 75 days after the date on  
17 which the approval of the first approved  
18 applicant’s application for the competitive  
19 generic therapy is made effective.”.

20 **SEC. 704. TROPICAL DISEASE PRODUCT APPLICATION.**

21 Subparagraph (A) of section 524(a)(4) of the Federal  
22 Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(4)) is  
23 amended—

24 (1) in clause (i), by striking “and” at the end;

1 (2) in clause (ii), by inserting “and” after the  
2 semicolon at the end; and

3 (3) by adding at the end the following:

4 “(iii) that contains reports of one or  
5 more new clinical investigations (other  
6 than bio-availability studies) that are es-  
7 sential to the approval of the application  
8 and conducted or sponsored by the sponsor  
9 of such application; and

10 “(iv) that contains an attestation  
11 from the sponsor of the application that  
12 such reports were not submitted as part of  
13 an application for marketing approval or li-  
14 censure by a regulatory authority in India,  
15 Brazil, Thailand, or any country that is a  
16 member of the Pharmaceutical Inspection  
17 Convention or the Pharmaceutical Inspec-  
18 tion Cooperation Scheme prior to Sep-  
19 tember 27, 2007.”.

20 **SEC. 705. GAO STUDY OF ISSUES REGARDING FIRST CYCLE**  
21 **APPROVALS OF GENERIC MEDICINES.**

22 (a) **STUDY BY GAO.**—The Comptroller General of  
23 the United States shall conduct a study to determine the  
24 following:

1           (1) The rate of first cycle approvals and ten-  
2           tative approvals for generic drug applications sub-  
3           mitted during the period beginning on October 1,  
4           2012, and ending on September 30, 2017. The rate  
5           of first cycle approvals and tentative approvals shall  
6           be determined and reported per each GDUFA cohort  
7           year during this period.

8           (2) If the rate determined pursuant to para-  
9           graph (1) for any GDUFA cohort year is lower than  
10          20 percent, the reasons contributing to the relatively  
11          low rate of first cycle approvals and tentative ap-  
12          provals for generic drug applications shall be  
13          itemized, assessed, and reported. In making the as-  
14          sessment required by this paragraph, the Comp-  
15          troller General shall consider, among other things,  
16          the role played by—

17                   (A) the Food and Drug Administration's  
18                   implementation of approval standards for ge-  
19                   neric drug applications;

20                   (B) the extent to which those approval  
21                   standards are communicated clearly to industry  
22                   and applied consistently during the review proc-  
23                   ess;

24                   (C) the procedures for reviewing generic  
25                   drug applications, including timelines for review



1 activities by the Food and Drug Administra-  
2 tion;

3 (D) the extent to which those procedures  
4 are followed consistently (and those timelines  
5 are met) by the Food and Drug Administration;

6 (E) the processes and practices for com-  
7 munication between the Food and Drug Admin-  
8 istration and sponsors of generic drug applica-  
9 tions; and

10 (F) the completeness and quality of origi-  
11 nal generic drug applications submitted to the  
12 Food and Drug Administration.

13 (3) Taking into account the determinations  
14 made pursuant to paragraphs (1) and (2) and any  
15 review process improvements implemented pursuant  
16 to this Act, whether there are ways the review proc-  
17 ess for generic drugs could be improved to increase  
18 the rate of first cycle approvals and tentative ap-  
19 provals for generic drug applications. In making this  
20 determination, the Comptroller General shall con-  
21 sider, among other things, options for increasing re-  
22 view efficiency and communication effectiveness.

23 (b) COMPLETION DATE.—Not later than the expira-  
24 tion of the 2-year period beginning on the date of enact-  
25 ment of this Act, the Comptroller General shall complete

1 the study under subsection (a) and submit a report de-  
2 scribing the findings and conclusions of the study to the  
3 Secretary, the Committee on Energy and Commerce of the  
4 House of Representatives, and the Committee on Health,  
5 Education, Labor, and Pensions of the Senate.

6 (c) DEFINITIONS.—For purposes of this section:

7 (1) The term “GDUFA cohort year” means a  
8 fiscal year.

9 (2) The term “generic drug” means a drug that  
10 is approved or is seeking approval under section  
11 505(j) of the Federal Food, Drug, and Cosmetic Act  
12 (21 U.S.C. 355(j)).

13 (3) The term “generic drug application” means  
14 an abbreviated new drug application for the approval  
15 of a generic drug under section 505(j) of the Fed-  
16 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
17 355(j)).

18 (4) The term “Secretary” means the Secretary  
19 of Health and Human Services.

20 (5)(A) The term “first cycle approvals and ten-  
21 tative approvals” means the approval or tentative  
22 approval of a generic drug application after the  
23 Food and Drug Administration’s complete review of  
24 the application and without issuance of one or more  
25 complete response letters.

1           (B) For purposes of this paragraph, the term  
2           “complete response letter” means a written commu-  
3           nication to the sponsor of a generic drug application  
4           or holder of a drug master file (DMF) from the  
5           Food and Drug Administration describing all of the  
6           deficiencies that the Administration has identified in  
7           the generic drug application (including pending  
8           amendments) or drug master file that must be satis-  
9           factorily addressed before the generic drug applica-  
10          tion can be approved.

