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:

''(B) Such term does not include a personal sound amplification product intended to amplify sound for non-hearing impaired consumers in situations including, hunting and bird-watching.''.

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

(C) include requirements for appropriate labeling of the over-the-counter hearing aid, including requirements that such labeling include a conspicuous statement that the device is only intended for adults over the age of 18, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed physician; and

Page 97, line 10, strike ''applicable'' and insert ''related''.

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

(5) NO EFFECT ON PRIVATE REMEDIES.—Nothing in this section shall be construed to modify or otherwise affect the ability of any person to exercise

a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

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

(d) REPORT.—Not later than 2 years after the date on which the final regulations described in subsection (b)(1) are issued, the Secretary of Health and Human Services shall submit to Congress a report analyzing any adverse events relating to over-the-counter hearing aids (as defined in subsection (p)(1) of section 520 of the Federal 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-disciplinary'' 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:

SEC. 703. INCENTIVIZING COMPETITIVE GENERIC THERAPY DEVELOPMENT.

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

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

''(v) 180-DAY EXCLUSIVITY PERIOD FOR COMPETITIVE GENERIC THERAPIES.—

''(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

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

received an exclusivity period under subclause (I).

"(III) DEFINITIONS.—In this clause and subparagraph (D)(iv):

"(aa) The term 'competitive generic therapy' means a drug—

"(AA) that is designated as a competitive generic therapy under section 506H; and

"(BB) for which there are no unexpired patents or blocking exclusivities on the list of products described in section 505(j)(7)(A) at the time of approval.

"(bb) The term 'first approved applicant' means any applicant that has submitted an application that—

"(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

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

the application for the competitive generic therapy; and

''(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).''; and

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

''(iv) SPECIAL FORFEITURE RULE FOR COMPETITIVE GENERIC THERAPY.—The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.''.

SEC. 704. TROPICAL DISEASE PRODUCT APPLICATION.

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

(1) in clause (i), by striking ''and'' at the end;

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

(3) by adding at the end the following:

''(iii) that contains reports of one or more new clinical investigations (other than bio-availability studies) that are essential to the approval of the application and conducted or sponsored by the sponsor of such application; and

''(iv) that contains an attestation from the sponsor of the application that such reports were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007.''.

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

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

(1) The rate of first cycle approvals and tentative approvals for generic drug applications submitted during the period beginning on October 1, 2012, and ending on September 30, 2017. The rate of first cycle approvals and tentative approvals shall be determined and reported per each GDUFA cohort year during this period.

(2) If the rate determined pursuant to paragraph (1) for any GDUFA cohort year is lower than 20 percent, the reasons contributing to the relatively low rate of first cycle approvals and tentative approvals for generic drug applications shall be itemized, assessed, and reported. In making the assessment required by this paragraph, the Comptroller General shall consider, among other things, the role played by—

(A) the Food and Drug Administration's implementation of approval standards for generic drug applications;

(B) the extent to which those approval standards are communicated clearly to industry and applied consistently during the review process;

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

activities by the Food and Drug Administration;

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

(E) the processes and practices for communication between the Food and Drug Administration and sponsors of generic drug applications; and

(F) the completeness and quality of original generic drug applications submitted to the Food and Drug Administration.

(3) Taking into account the determinations made pursuant to paragraphs (1) and (2) and any review process improvements implemented pursuant to this Act, whether there are ways the review process for generic drugs could be improved to increase the rate of first cycle approvals and tentative approvals for generic drug applications. In making this determination, the Comptroller General shall consider, among other things, options for increasing review efficiency and communication effectiveness.

(b) COMPLETION DATE.—Not later than the expiration of the 2-year period beginning on the date of enactment of this Act, the Comptroller General shall complete

the study under subsection (a) and submit a report describing the findings and conclusions of the study to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

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

(1) The term ''GDUFA cohort year'' means a fiscal year.

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

(3) The term ''generic drug application'' means an abbreviated new drug application for the approval of a generic drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(4) The term ''Secretary'' means the Secretary of Health and Human Services.

(5)(A) The term ''first cycle approvals and tentative approvals'' means the approval or tentative approval of a generic drug application after the Food and Drug Administration's complete review of the application and without issuance of one or more complete response letters.

(B) For purposes of this paragraph, the term ''complete response letter'' means a written communication to the sponsor of a generic drug application or holder of a drug master file (DMF) from the Food and Drug Administration describing all of the deficiencies that the Administration has identified in the generic drug application (including pending amendments) or drug master file that must be satisfactorily addressed before the generic drug application can be approved.

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