AMENDMENT TO H.R. ____

OFFERED BY MR. SCHRADER OF OREGON

At the appropriate place, insert the following:

TITLE ____—GENERIC DRUG ACCESS AND COMPETITION

SEC. ___. COMPETITIVE GENERIC THERAPIES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506G the following:

"SEC. 506H. COMPETITIVE GENERIC THERAPIES.

''(a) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug that is designated as a competitive generic therapy pursuant to paragraph (2), expedite the development and review of such drug pursuant to section 505(j).

''(b) DESIGNATION PROCESS.—

''(1) REQUEST.—The sponsor of a drug may request the Secretary to designate the drug as a competitive generic therapy.

''(2) TIMING.—A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 505(j).

''(3) CRITERIA.—A drug is eligible for designation as a competitive generic therapy if the Secretary determines that there is inadequate generic competition.

''(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary shall—

''(A) determine whether the drug that is the subject of the request meets the criteria described in paragraph (3); and

''(B) if the Secretary finds that the drug meets such criteria, designate the drug as a competitive generic therapy.

''(c) ACTIONS.—In expediting the development and review of a drug under subsection (a), the Secretary shall, as appropriate, take actions including the following:

''(1) Hold meetings with the sponsor and the review team throughout the development of the drug prior to submission of the application for such drug under section 505(j).

''(2) Provide timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical

data necessary for approval is as efficient as practicable.

''(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review, including with respect to drug-device combination products and other complex products.

''(4) Assign a cross-disciplinary project lead for the Food and Drug Administration review team—

''(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

''(B) to serve as a scientific liaison between the review team and the sponsor.

''(d) DEFINITIONS.—In this section:

''(1) The term 'generic drug' means a drug that is approved pursuant to section 505(j).

''(2) The term 'inadequate generic competition' means there is not more than one approved drug product on the list of products described in section 505(j)(7)(A) (not including products on the discontinued section of such list) that is—

''(A) the reference listed drug; or

''(B) a generic drug with the same reference listed drug as the drug for which des-

ignation as a competitive generic therapy is sought.

''(3) The term 'reference listed drug' means the listed drug (as such term is used in section 505(j)) for the drug involved.''.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) ISSUANCE.—The Secretary of Health and Human Services shall—

(i) not later than 18 months after the date of enactment of this Act, issue draft guidance on the provisions of section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a); and

(ii) not later than 1 year after the close of the comment period for the draft guidance, issue final guidance on such provisions.

(B) CONTENTS.—The guidance issued under this subsection shall—

(i) specify the process and criteria by which the Secretary makes a designation under section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

(ii) specify the actions the Secretary will take to expedite the development and review of a competitive generic therapy pursuant to such a designation; and

(iii) include good review management practices for competitive generic therapies.

(2) AMENDED REGULATIONS.—

(A) IN GENERAL.—If the Secretary of Health and Human Services determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations, in order to implement section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(B) PROCEDURE.—In carrying out subparagraph (A), and in issuing any other regulations to implement such section 506H, the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

(iii) publish the final regulation not less than 30 days before the effective date of the regulation.

SEC. ___. ENHANCING REGULATORY TRANSPARENCY TO ENHANCE GENERIC COMPETITION.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(11) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall—

''(A) by telephone or electronic mail, provide review status updates; and

''(B) indicate in such updates the categorical status of the applications by each relevant review discipline.''.

SEC. _____. 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.—If the application is for a competitive generic therapy, 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.

''(II) DEFINITION.—In this clause and subparagraph (D)(iv), 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 blocking patents or exclusivities on the list of products described in section 505(j)(7)(A).''; 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 the holder of the approved abbreviated ap-

plication for the competitive generic therapy involved if the holder fails to market the competitive generic therapy within 75 days after the date on which the approval of the application is made effective.''.

SEC. ___. 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—

''(I) are essential to the approval of the application and conducted or sponsored by the applicant; and

''(II) were not relied upon for marketing authority by a foreign national regulatory authority prior to September 27, 2007.''.

SEC. ___. 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 con-

sider, among other things, options for increasing review efficiency and communication effectiveness.

(b) CONSULTATION.—The Comptroller General shall conduct the study under subsection (a) in consultation with—

(1) the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs; and

(2) sponsors of generic drug applications and organizations representing sponsors of generic drug applications.

(c) INITIATION AND COMPLETION DATES.—Not later than 90 days after the date of enactment of this Act, the Comptroller General shall initiate the study under subsection (a). 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.

(d) 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 satis-

factorily addressed before the generic drug application can be approved.