AMENDMENT NO._____ Calendar No._____

Purpose: To provide for increased transparency in generic drug applications.

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

S. 1114

To amend the Federal Food, Drug, and Cosmetic Act with respect to the 180-day exclusivity period.

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 Ms. HASSAN (for herself, Mr. PAUL, Mr. BRAUN, and Mr. HICKENLOOPER)

Viz:

At the appropriate place, insert the following:

SEC. ___. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) IN GENERAL.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is amended by adding at the end the following:

''(H)(i) Upon request (in controlled correspondence or an analogous process) by a person that has submitted or intends to submit an abbreviated application under this subsection for a drug that is required by regulation to contain one or more of the same inactive ingredients in the

same concentration as the listed drug referred to, or for which the Secretary determines there is a scientific justification for an approach that is in vitro in whole or in part to be used to demonstrate bioequivalence for a drug if such a drug contains one or more of the same inactive ingredients in the same concentration as the listed drug referred to, or on the Secretary's own initiative during the review of an application under this subsection for such a drug, the Secretary shall inform the person whether such drug is qualitatively and quantitatively the same as the listed drug.

''(ii) Notwithstanding section 301(j), if the Secretary determines that such drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

''(I) the ingredient or ingredients that cause the drug not to be qualitatively or quantitatively the same as the listed drug; and

''(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

''(iii) If the Secretary determines that such drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such deter-

mination after the submission of an abbreviated application for such drug under this subsection unless—

''(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

''(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

''(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

''(v) Except as set forth in clauses (i) and (ii), nothing in this subparagraph shall be construed to authorize the disclosure of nonpublic qualitative or quantitative information about the ingredients in a listed drug, or to affect the status, if any, of such information as trade secret or confidential commercial information for purposes of section 301(j) of this Act, section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Sec-

retary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a drug is qualitatively and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance under this subsection, the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.