

Maggie Hassan
Hassan S. 4348 Amendment #1

AMENDMENT NO. _____ Calendar No. _____

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

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, 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 Ms. HASSAN (for herself and Mr. PAUL)

Viz:

1 At the appropriate place in title V, insert the fol-
2 lowing:

3 **SEC. 5 _____. INCREASING TRANSPARENCY IN GENERIC**
4 **DRUG APPLICATIONS.**

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

8 “(H)(i) Upon request (in controlled correspondence
9 or otherwise) by a person that has submitted or intends
10 to submit an abbreviated application under this subsection

1 for a drug that is generally required by regulation or rec-
2 ommended in guidance to contain the same inactive ingre-
3 dients in the same concentration as the listed drug re-
4 ferred to or for which there is a scientific justification that
5 an in vitro approach can be used to demonstrate bio-
6 equivalence based on certain qualitative or quantitative
7 criteria with respect to an inactive ingredient, or on the
8 Secretary's own initiative during the review of an applica-
9 tion under this subsection for such a drug, the Secretary
10 shall inform the person whether such drug is qualitatively
11 and quantitatively the same as the listed drug.

12 “(ii) If the Secretary determines that such drug is
13 not qualitatively or quantitatively the same as the listed
14 drug, the Secretary shall identify and disclose to the per-
15 son—

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

19 “(II) for any ingredient for which there is an
20 identified quantitative deviation, the amount of such
21 deviation.

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

1 mination after the submission of an abbreviated applica-
2 tion for such drug under this subsection unless—

3 “(I) the formulation of the listed drug has been
4 changed and the Secretary has determined that the
5 prior listed drug formulation was withdrawn for rea-
6 sons of safety or effectiveness; or

7 “(II) the Secretary makes a written determina-
8 tion that the prior determination must be changed
9 because an error has been identified.

10 “(iv) If the Secretary makes a written determination
11 described in clause (iii)(II), the Secretary shall provide no-
12 tice and a copy of the written determination to the person
13 making the request under clause (i).

14 “(v) The disclosures required by this subparagraph
15 are disclosures authorized by law, including for purposes
16 of section 1905 of title 18, United States Code.”.

17 (b) GUIDANCE.—

18 (1) IN GENERAL.—Not later than one year
19 after the date of enactment of this Act, the Sec-
20 retary of Health and Human Services shall issue
21 draft guidance, or update guidance, describing how
22 the Secretary will determine whether a drug is quali-
23 tatively and quantitatively the same as the listed
24 drug (as such terms are used in section
25 505(j)(3)(H) of the Federal Food, Drug, and Cos-

1 metec Act, as added by subsection (a)), including
2 with respect to assessing pH adjusters.

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

6 (A) publish draft guidance;

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

9 (C) after considering any comments re-
10 ceived and not later than one year after the
11 close of the comment period on the draft guid-
12 ance, publish final guidance.

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