

119TH CONGRESS  
1ST SESSION

# S. 1302

To provide for increased transparency in generic drug applications.

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IN THE SENATE OF THE UNITED STATES

APRIL 3, 2025

Ms. HASSAN (for herself, Mr. PAUL, Mr. HICKENLOOPER, and Mr. LEE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To provide for increased transparency in generic drug applications.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Increasing Trans-  
5 parency in Generic Drug Applications Act”.

6 **SEC. 2. INCREASING TRANSPARENCY IN GENERIC DRUG**  
7 **APPLICATIONS.**

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

1       “(H)(i) Upon request (in controlled correspondence  
2 or an analogous process) by a person that has submitted  
3 or intends to submit an abbreviated application under this  
4 subsection for a drug that is required by regulation to con-  
5 tain one or more of the same inactive ingredients in the  
6 same concentrations as the listed drug referred to, or for  
7 which the Secretary determines there is a scientific jus-  
8 tification for an approach that is in vitro, in whole or in  
9 part, to be used to demonstrate bioequivalence for a drug  
10 if such a drug contains one or more of the same inactive  
11 ingredients in the same concentrations as the listed drug  
12 referred to, the Secretary shall inform the person whether  
13 such drug is qualitatively and quantitatively the same as  
14 the listed drug. The Secretary may also provide such infor-  
15 mation to such a person on the Secretary’s own initiative  
16 during the review of an abbreviated application under this  
17 subsection for such drug.

18       “(ii) Notwithstanding section 301(j), if the Secretary  
19 determines that such drug is not qualitatively or quan-  
20 titatively the same as the listed drug, the Secretary shall  
21 identify and disclose to the person—

22               “(I) the ingredient or ingredients that cause  
23 such drug not to be qualitatively or quantitatively  
24 the same as the listed drug; and

1           “(II) for any ingredient for which there is an  
2           identified quantitative deviation, the amount of such  
3           deviation.

4           “(iii) If the Secretary determines that such drug is  
5           qualitatively and quantitatively the same as the listed  
6           drug, the Secretary shall not change or rescind such deter-  
7           mination after the submission of an abbreviated applica-  
8           tion for such drug under this subsection unless—

9           “(I) the formulation of the listed drug has been  
10          changed and the Secretary has determined that the  
11          prior listed drug formulation was withdrawn for rea-  
12          sons of safety or effectiveness; or

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

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

20          “(v) The disclosures authorized under clauses (i) and  
21          (ii) are disclosures authorized by law, including for pur-  
22          poses of section 1905 of title 18, United States Code. This  
23          subparagraph shall not otherwise be construed to author-  
24          ize the disclosure of nonpublic qualitative or quantitative  
25          information about the ingredients in a listed drug, or to

1 affect the status, if any, of such information as trade se-  
2 cret or confidential commercial information for purposes  
3 of section 301(j) of this Act, section 552 of title 5, United  
4 States Code, or section 1905 of title 18, United States  
5 Code.”.

6 (b) GUIDANCE.—

7 (1) IN GENERAL.—Not later than one year  
8 after the date of enactment of this Act, the Sec-  
9 retary of Health and Human Services shall issue  
10 draft guidance, or update guidance, describing how  
11 the Secretary will determine whether a drug is quali-  
12 tatively and quantitatively the same as the listed  
13 drug (as such terms are used in section  
14 505(j)(3)(H) of the Federal Food, Drug, and Cos-  
15 metic Act, as added by subsection (a)), including  
16 with respect to assessing pH adjusters.

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

20 (A) publish draft guidance;

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

23 (C) after considering any comments re-  
24 ceived and not later than one year after the

1           close of the comment period on the draft guid-  
2           ance, publish final guidance.

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

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