

118TH CONGRESS
1ST SESSION

S. 775

To provide for increased transparency in generic drug applications.

IN THE SENATE OF THE UNITED STATES

MARCH 14, 2023

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

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

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

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

22 “(II) for any ingredient for which there is an
23 identified quantitative deviation, the amount of such
24 deviation.

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

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8 prior listed drug formulation was withdrawn for rea-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

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

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

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

20 (b) GUIDANCE.—

21 (1) IN GENERAL.—Not later than one year
22 after the date of enactment of this Act, the Sec-
23 retary of Health and Human Services shall issue
24 draft guidance, or update guidance, describing how
25 the Secretary will determine whether a drug is quali-

1 tatively and quantitatively the same as the listed
2 drug (as such terms are used in section
3 505(j)(3)(H) of the Federal Food, Drug, and Cos-
4 metic Act, as added by subsection (a)), including
5 with respect to assessing pH adjusters.

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

9 (A) publish draft guidance;

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

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

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

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