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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R.

To amend section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) with respect to a process to inform persons submitting an abbreviated application for a new drug whether the new drug is qualitatively or quantitatively the same as a listed drug, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. KUSTER of New Hampshire introduced the following bill; which was referred to the Committee on _____

A BILL

To amend section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) with respect to a process to inform persons submitting an abbreviated application for a new drug whether the new drug is qualitatively or quantitatively the same as a listed drug, and for other purposes.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Increasing Trans-
3 parency in Generic Drug Applications Act of 2022”.

4 **SEC. 2. DETERMINING WHETHER PROPOSED NEW GENERIC**
5 **DRUGS ARE QUALITATIVELY OR QUAN-**
6 **TITATIVELY THE SAME AS THE LISTED DRUG.**

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

10 “(H)(i) Upon request (in controlled correspondence
11 or otherwise) by a person that has submitted or intends
12 to submit an abbreviated application for a new drug under
13 this subsection or on the Secretary’s own initiative during
14 the review of such abbreviated application, the Secretary
15 shall inform the person whether such new drug is quali-
16 tatively and quantitatively the same as the listed drug.

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

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

24 “(II) the quantity or proportion of any ingre-
25 dient in the listed drug for which there is an identi-
26 fied quantitative deviation.

1 “(iii) If the Secretary determines that such new drug
2 is 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 new 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 under section 1905 of
19 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 guidance describing how the Secretary will deter-
25 mine whether a new drug is qualitatively and quan-

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

6 (2) PROCESS.—In issuing guidance as required
7 by paragraph (1), the Secretary of Health and
8 Human 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, publish final guidance.

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