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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.

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IN THE HOUSE OF REPRESENTATIVES

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

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# 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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Increasing Transparency in Generic Drug Applications Act of 2022''.

**SEC. 2. DETERMINING WHETHER PROPOSED NEW GENERIC DRUGS ARE QUALITATIVELY OR QUANTITATIVELY THE SAME AS THE LISTED DRUG.**

(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 otherwise) by a person that has submitted or intends to submit an abbreviated application for a new drug under this subsection or on the Secretary's own initiative during the review of such abbreviated application, the Secretary shall inform the person whether such new drug is qualitatively and quantitatively the same as the listed drug.

''(ii) If the Secretary determines that such new 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 new drug not to be qualitatively or quantitatively the same as the listed drug; and

''(II) the quantity or proportion of any ingredient in the listed drug for which there is an identified quantitative deviation.

''(iii) If the Secretary determines that such new drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such new 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) The disclosures required by this subparagraph are disclosures authorized by law under 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 Secretary of Health and Human Services shall issue guidance describing how the Secretary will determine whether a new drug is qualitatively and quan-

titatively 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 as required by paragraph (1), 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, 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.