

119TH CONGRESS
1ST SESSION

H. R. 1843

To amend the Federal Food, Drug, and Cosmetic Act to increase transparency
in generic drug applications.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2025

Mr. DUNN of Florida (for himself and Mr. MULLIN) introduced the following
bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
increase 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. 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 an analogous process) by a person that has submitted
10 or intends to submit an abbreviated application under this

1 subsection for a drug that is required by regulation to con-
2 tain one or more of the same inactive ingredients in the
3 same concentrations as the listed drug referred to, or for
4 which the Secretary determines there is a scientific jus-
5 tification for an approach that is in vitro in whole or in
6 part to be used to demonstrate bioequivalence for a drug
7 if such a drug contains one or more of the same inactive
8 ingredients in the same concentrations as the listed drug,
9 the Secretary shall inform the person whether such drug
10 is qualitatively and quantitatively the same as the listed
11 drug. The Secretary may also provide such information
12 to such a person on the Secretary's own initiative during
13 the review of an abbreviated application under this sub-
14 section for such drug.

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

19 “(I) the ingredient or ingredients that cause
20 such drug not to be qualitatively or quantitatively
21 the 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-

tatively and quantitatively 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 under this subsection, 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 and not later than one year after the close of the comment period on the draft guidance, 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.

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