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118TH CONGRESS
1ST SESSION

H. R. 1683

To amend the Federal Food, Drug, and Cosmetic Act to make certain changes with respect to the approval of abbreviated applications for the approval of new animal drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 21, 2023

Ms. MACE introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make certain changes with respect to the approval of abbreviated applications for the approval of new animal drugs, 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 ''Generic Animal Drug Advancement Act''.

SEC. 2. CHANGES TO PROCESS FOR APPROVAL OF ABBREVIATED APPLICATIONS FOR THE APPROVAL OF NEW ANIMAL DRUGS.

Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended—

(1) in subsection (d)(4), in the matter preceding subparagraph (A), by striking ''section 512(b)(1)'' and inserting ''paragraph (1) or (2) of subsection (b)'';

(2) in subsection (n)(1)(F)—

(A) by striking ''or because the new animal drug'' and inserting ''because the new animal drug''; and

(B) by striking ''manufacturers;'' and inserting ''manufacturers, or because the new animal drug is not shown to be bioequivalent to all of the species for which the approved new animal drug is approved for use;''; and

(3) by amending subsection (o) to read as follows:

''(o) For purposes of this section—

''(1) the term 'bioequivalent' means, in establishing whether a new animal drug is bioequivalent to an approved new animal drug—

"(A) demonstrating bioequivalence in at least one major species for which the approved new animal drug is approved for use; or

"(B) in the case that an approved new animal drug is not approved for use in any major species, demonstrating bioequivalence in at least one species for which the approved new animal drug is approved for use; and

"(2) the term 'patent' means a patent issued by the United States Patent and Trademark Office;".

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