

[117H8857]


(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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

Ms. MACE introduced the following bill; which was referred to the Committee
on _____

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.

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 “Generic Animal Drug
5 Advancement Act”.

1 **SEC. 2. CHANGES TO PROCESS FOR APPROVAL OF ABBRE-**
2 **VIATED APPLICATIONS FOR THE APPROVAL**
3 **OF NEW ANIMAL DRUGS.**

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

6 (1) in subsection (d)(4), in the matter pre-
7 ceding subparagraph (A), by striking “section
8 512(b)(1)” and inserting “paragraph (1) or (2) of
9 subsection (b)”;

10 (2) in subsection (n)(1)(F)—

11 (A) by striking “or because the new animal
12 drug” and inserting “because the new animal
13 drug”; and

14 (B) by striking “manufacturers;” and in-
15 serting “manufacturers, or because the new
16 animal drug is not shown to be bioequivalent to
17 all of the species for which the approved new
18 animal drug is approved for use;”; and

19 (3) by amending subsection (o) to read as fol-
20 lows:

21 “(o) For purposes of this section—

22 “(1) the term ‘bioequivalent’ means, in estab-
23 lishing whether a new animal drug is bioequivalent
24 to an approved new animal drug—

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

4 “(B) in the case that an approved new ani-
5 mal drug is not approved for use in any major
6 species, demonstrating bioequivalence in at least
7 one species for which the approved new animal
8 drug is approved for use; and

9 “(2) the term ‘patent’ means a patent issued by
10 the United States Patent and Trademark Office;”.