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115TH CONGRESS
2D SESSION

H. R. 5599

To amend the Federal Food, Drug, and Cosmetic Act to expand the conditional approval pathway for more animal drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 24, 2018

Mr. HUDSON (for himself, Mr. SCHRADER, Mr. BUCSHON, Mr. BUTTERFIELD, and Mr. MULLIN) 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 expand the conditional approval pathway for more 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 ''Animal Health and Innovation Act of 2018''.

SEC. 2. CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS.

Section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc) is amended—

(1) in the section heading, by striking ''**SPECIES**'' and inserting ''**SPECIES AND CERTAIN NEW ANIMAL DRUGS**'';

(2) in subsection (a)—

(A) by amending paragraph (1) to read as follows:

''(1)(A) Except as provided in paragraph (3), any person may file with the Secretary an application for conditional approval of—

''(i) a new animal drug intended for a minor use or a minor species; or

''(ii) a new animal drug not intended for a minor use or minor species—

''(I) that is intended to treat a serious or life-threatening disease or condition or addresses an unmet animal or human health need; and

''(II) for which the Secretary determines that a demonstration of effectiveness would require a complex or particularly difficult study or studies.

''(B) The Secretary shall, not later than September 30, 2019, issue guidance or regulations further clarifying the criteria specified in subparagraph (A)(ii).

''(C) An application under this paragraph shall comply in all respects with the provisions of section 512 except for subsections (a)(4), (b)(2), (c)(1), (c)(2), (c)(3), (d)(1), (e), (h), and (n) of such section unless otherwise stated in this section, and any additional provisions of this section.

''(D) New animal drugs conditionally approved under this section are subject to application of the same safety standards that would be applied to new animal drugs approved under section 512(d) (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).''; and

(B) in paragraph (3)—

(i) in subparagraph (A), by striking the period at the end and inserting ''or a new animal drug that is an antibiotic drug;''; and

(ii) in subparagraph (B), by striking ''; or'' and inserting ''; or''; and

(3) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''for the conditionally approved use'' after ''shall''; and

(B) in paragraph (2)—

(i) by striking ''An intended use'' and inserting ''The Secretary shall, through regulation or guidance, determine under what conditions an intended use''; and

(ii) by striking ''shall not'' and inserting ''may''.

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