AMENDMENT TO H.R. 5554

OFFERED BY MR. HUDSON OF NORTH CAROLINA

[Amendment instructions refer to version forwarded by the Subcommittee on Health on April 25, 2018]

Strike section 304 and insert the following:

SEC. 304. CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS.

(a) IN GENERAL.—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 (B), by striking ", or" and inserting "; or";

(ii) by redesignating subparagraphs (A), (B), and (C) as clauses (i), (ii), and (iii), respectively, and moving the margins of such clauses (as so redesignated) two ems to the right);

(iii) by striking "A person may not file" and inserting "(A) A person may not file"; and

(iv) by adding at the end the following new subparagraph:

"(B) A person may not file an application under paragraph (1)(A)(ii) if the application seeks conditional approval of a new animal drug that contains an antimicrobial active ingredient."; 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''.

(b) REPORT ON INCORPORATING VETERINARY OVERSIGHT.—Not later than September 30, 2019, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate identifying how the Food and Drug Administration will incorporate veterinary oversight for all approved medically important antimicrobial drugs administered to animals that are not yet subject veterinary oversight. Such report shall address requirements related to revisions of labeling to reflect that medically important antimicrobial drugs administered to animals shall be subject to veterinary oversight.

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