AMENDMENT

OFFERED BY MS. SCHAKOWSKY OF ILLINOIS

At the end of title II, add the following (and make such technical and conforming amendments as may be necessary):

SEC. ___. PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS.

(a) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(rr) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—The term 'critical antimicrobial animal drug' means a drug that—

''(1) is intended for use in food-producing animals; and

''(2) is composed wholly or partly of—

''(A) any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, or sulfonamide; or

''(B) any other drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection caused by microorganisms.

''(ss) NONTHERAPEUTIC USE.—The term 'nontherapeutic use', with respect to a critical antimicrobial animal drug, means any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose.''.

(b) APPLICATIONS PENDING OR SUBMITTED AFTER ENACTMENT.—Section 512(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)) is amended—

(1) in the first sentence—

(A) in subparagraph (H), by striking ''or'' at the end;

(B) by redesignating subparagraph (I) as subparagraph (J); and

(C) by inserting after subparagraph (H) the following:

''(I) with respect to a critical antimicrobial animal drug or a drug of the same chemical class as a critical antimicrobial animal drug, the applicant has failed to demonstrate that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable, in

whole or in part, to the nontherapeutic use of the drug; or''; and

(2) in the second sentence, by striking ''(A) through (I)'' and inserting ''(A) through (J)''.

(c) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IMPORTANT FOR HUMAN HEALTH.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

''(q) PHASED ELIMINATION OF NONTHERAPEUTIC USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS IMPORTANT FOR HUMAN HEALTH.—

''(1) APPLICABILITY.—This subsection applies to the nontherapeutic use in a food-producing animal of a drug—

''(A)(i) that is a critical antimicrobial animal drug; or

''(ii) that is of the same chemical class as a critical antimicrobial animal drug; and

''(B)(i) for which there is in effect an approval of an application or an exemption under subsection (b), (i), or (j) of section 505; or

''(ii) that is otherwise marketed for use.

''(2) WITHDRAWAL.—The Secretary shall withdraw the approval of a nontherapeutic use in food-

producing animals described in paragraph (1) on the date that is 2 years after the date of enactment of this subsection unless—

''(A) before the date that is 2 years after the date of the enactment of this subsection, the Secretary makes a final written determination that the holder of the approved application has demonstrated that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug; or

''(B) before the date specified in subparagraph (A), the Secretary makes a final written determination under this subsection, with respect to a risk analysis of the drug conducted by the Secretary and other relevant information, that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug.

''(3) EXEMPTIONS.—Except as provided in paragraph (5), if the Secretary grants an exemption under section 505(i) for a drug that is a critical

antimicrobial animal drug, the Secretary shall rescind each approval of a nontherapeutic use in a food-producing animal of the critical antimicrobial animal drug, or of a drug in the same chemical class as the critical antimicrobial animal drug, as of the date that is 2 years after the date on which the Secretary grants the exemption.

''(4) APPROVALS.—Except as provided in paragraph (5), if an application for a drug that is a critical antimicrobial animal drug is submitted to the Secretary under section 505(b), the Secretary shall rescind each approval of a nontherapeutic use in a food-producing animal of the critical antimicrobial animal drug, or of a drug in the same chemical class as the critical antimicrobial animal drug, as of the date that is 2 years after the date on which the application is submitted to the Secretary.

''(5) EXCEPTION.—Paragraph (3) or (4), as the case may be, shall not apply if—

''(A) before the date on which approval would be rescinded under that paragraph, the Secretary makes a final written determination that the holder of the application for the approved nontherapeutic use has demonstrated that there is a reasonable certainty of no harm

to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use in the food-producing animal of the critical antimicrobial animal drug; or

''(B) before the date specified in subparagraph (A), the Secretary makes a final written determination under this subsection, with respect to a risk analysis of the critical antimicrobial animal drug conducted by the Secretary and any other relevant information, that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug.''.