I

107TH CONGRESS
2D SESSION

H. R. 3804

To amend the Federal Food, Drug, and Cosmetic Act to ensure that use of certain antibiotic drugs in animal agriculture does not compromise human health by contributing to the development of antibiotic resistance.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 27, 2002

Mr. BROWN of Ohio (for himself, Mr. WAXMAN, and Ms. SLAUGHTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that use of certain antibiotic drugs in animal agriculture does not compromise human health by contributing to the development of antibiotic resistance.

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 ''Preservation of Antibiotics for Human Treatment Act of 2002''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Several antibiotics and classes of antibiotics, particularly penicillins, tetracyclines, macrolides (including but not limited to erythromycin and tylosin), lincomycin, bacitracin, virginiamycin, aminoglycosides, and sulfonamides, that either are used in or are related to antibiotics used in humans to treat infectious diseases are also routinely administered to healthy agricultural animals, generally via feed or water, in order to promote the animals' growth or to prevent disease. Such uses do not require a veterinarian's prescription.

(2) Mounting scientific evidence shows that this nontherapeutic use of antibiotics in agricultural animals can lead to development of antibiotic-resistant bacteria that can be transferred to people, making it harder to treat certain infections.

(3) In 1969, the Swann Committee was formed in the United Kingdom to examine the public health effects of use of antimicrobial drugs in food-producing animals. The Committee recommended that antimicrobials be divided into ''feed'' and ''therapeutic'' classes of drugs and that the ''feed'' class not include drugs used therapeutically in humans or animals. Most developed countries in the world, with the exception of the United States and Canada, re-

strict the use of antimicrobials in animal production systems for growth promotion.

(4) In 1997, the World Health Organization recommended that antibiotics used to treat humans should not also be used to promote animal growth, although such antibiotics could still be used to treat ill animals.

(5) In July 1998, the National Academy of Sciences, in a report prepared at the request of the United States Department of Agriculture and the Food and Drug Administration, concluded ''there is a link between the use of antibiotics in food animals, the development of bacterial resistance to these drugs, and human disease''.

(6) In December 1998, health ministers for the European Union countries voted to ban the remaining human-use antibiotics still in use to promote animal growth. The ban on using virginiamycin, tylosin, spiramycin, and bacitracin in animal feed became effective for the 15 member states of the European Union on July 1, 1999. Prior to that action, individual European countries, including the United Kingdom, Denmark, Finland, and Sweden, had banned the use in animal feed of specific antibiotics.

(7) An April 1999 study by the General Accounting Office concluded that resistant strains of three microorganisms that cause foodborne illness or disease in humans—salmonella, campylobacter, and E. coli—are linked to the use of antibiotics in animals.

(8) In October 2000, the Food and Drug Administration issued a notice announcing its intention to withdraw approvals for use of fluoroquinolone antibiotics in poultry, in light of the fact that increased resistance to fluoroquinolones in certain bacteria followed approval of those antibiotics for such use in the mid-1990s. While one company (Abbott Laboratories) immediately agreed to voluntarily withdraw its product, the only other manufacturer (Bayer Corp.) is contesting FDA's proposed withdrawal and continues to market its product. Previous proceedings by FDA to withdraw approval of animal drugs have taken substantial amounts of time following initiation of formal action by FDA, including 6 years in one instance and 20 in another.

(9) In November 2000, the American Medical Association, American Public Health Association, and other health organizations urged Bayer Corp. to comply voluntarily with FDA's proposed ban.

(10) In June 2001, the American Medical Association adopted a resolution opposing nontherapeutic use of antimicrobials in animal agriculture. Organizations that have taken a similar position include the American College of Preventive Medicine, the American Public Health Association, and the Council of State and Territorial Epidemiologists.

(11) In October 2001, the New England Journal of Medicine published a guest editorial titled ''Antimicrobials in Animal Feed—Time to Stop''. The editorial urged a ban on nontherapeutic use in animals of medically important antibiotics, and on use in animals of fluoroquinolones.

(12) In January 2001, a Federal Interagency Task Force released an Action Plan, which notes that ''drug-resistant pathogens are a growing menace to all people, regardless of age, gender, or socioeconomic background. If we do not act to address the problem . . . [d]rug choices for the treatment of common infections will become increasingly limited and expensive—and, in some cases, nonexistent.''.

(13) Scientific studies have shown that resistance traits can be transferred among unrelated species of bacteria, including from nonpathogens to pathogens.

SEC. 3. REQUIRING PROOF OF SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS.

(a) NONTHERAPEUTIC USE; APPLICATIONS PENDING ON 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 subparagraph (H), by striking ''or'' at the end;

(2) by redesignating subparagraph (I) as subparagraph (J);

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

''(I) such drug is an antimicrobial new animal drug and 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 such drug; or''; and

(4) in the matter after and below subparagraph (J) (as redesignated by paragraph (2) of this subsection), by striking ''(A) through (I)'' and inserting ''(A) through (J)''.

(b) NONTHERAPEUTIC USE; RESCINDING OF APPROVAL FOR CERTAIN CURRENTLY APPROVED DRUGS.—Section 512 of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 360b) is amended by adding at the end the following subsection:

''(q) With respect to each antimicrobial new animal drug for which, as of the day before the date of the enactment of the Preservation of Antibiotics for Human Treatment Act of 2002, there was in effect an approval of an application filed pursuant to subsection (b), the approval of a nontherapeutic use of such drug (including use through animal feed that bears or contains such drug) is subject to the following, as applicable:

''(1) In the case of penicillins, tetracyclines, macrolides (including but not limited to erythromycin and tylosin), lincomycin, bacitracin, virginiamycin, aminoglycosides, and sulfonamides:

''(A) Each approval of a nontherapeutic use of any of such drugs in an animal is rescinded upon the expiration of the two-year period beginning on such date of enactment unless, before the expiration of such period, the Secretary determines 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 such drug.

''(B) In carrying out subparagraph (A), the Secretary may not consider any data regarding the antimicrobial new animal drug involved that is submitted to the Secretary after the expiration of the 180-day period beginning on such date of enactment, unless such data were not available for submission within such 180-day period.

''(C) If pursuant to subparagraph (A) the Secretary determines, with respect to the antimicrobial new animal drug involved, that there is not a reasonable certainty of no harm to human health, the Secretary may issue an order withdrawing approval of such drug at any time before the date on which the drug would be rescinded under such subparagraph.

''(2) In the case of an antimicrobial new animal drug that is not referred to in paragraph (1):

''(A) If the Secretary grants an exemption under section 505(i) regarding such a drug, or a drug with substantially the same active ingredients, each approval of a nontherapeutic use of such new animal drug in an animal is rescinded upon the expiration of the two-year period beginning on the date on which the Secretary pro-

vides notice in accordance with subparagraph (C) regarding the new animal drug, except as provided in subparagraph (D). Such notice shall be so provided not later than 10 days after the date on which the Secretary grants the exemption under section 505(i).

''(B) If an application for such a drug, or a drug with substantially the same active ingredients, is submitted to the Secretary under section 505(b) or under section 351 of the Public Health Service Act, and the Secretary has not previously granted an exemption under section 505(i) regarding the drug, each approval of a nontherapeutic use of such new animal drug in an animal is rescinded upon the expiration of the two-year period beginning on the date on which the Secretary provides notice in accordance with subparagraph (C) regarding the new animal drug, except as provided in subparagraph (D). Such notice shall be so provided not later than 10 days after the date on which the Secretary receives the application under section 505(b) or under such section 351, as the case may be.

"(C) For purposes of subparagraph (A) and (B), notice regarding the antimicrobial new animal drug involved is provided in accordance with this subparagraph if the Secretary informs the holder of the approved application for the nontherapeutic use of such drug, in writing, of the applicability of this paragraph to such application (including that approval of the application will be rescinded, except as provided in subparagraph (D), and including the opportunity under subparagraph (E) to submit data).

"(D) Subparagraph (A) or (B), as the case may be, applies to the antimicrobial new animal drug involved unless, before the date on which approval would be rescinded under such subparagraph, the Secretary determines 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 such drug.

"(E) In carrying out subparagraph (A) or (B), the Secretary may not consider any data regarding the antimicrobial new animal drug in-

volved that is submitted to the Secretary after the expiration of the 180-day period beginning on the date on which the Secretary provides notice in accordance with subparagraph (C) to the holder of the approved application for the nontherapeutic use of such drug.

''(F) If pursuant to subparagraph (A) or (B) the Secretary determines, with respect to the antimicrobial new animal drug involved, that there is not a reasonable certainty of no harm to human health, the Secretary may issue an order withdrawing approval of such drug at any time before the date on which the drug would be rescinded under such subparagraph.''.

(c) ALL USES OF FLUOROQUINOLONES IN POULTRY; RESCINDING OF APPROVAL FOR CURRENTLY APPROVED DRUGS.—Section 512 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b) of this section, is amended by adding at the end the following:

''(r) With respect to a fluoroquinolone for which, as of the day before the date of the enactment of the Preservation of Antibiotics for Human Treatment Act of 2002, there was in effect an approval of an application filed pursuant to subsection (b), the use of such drug (including

use through animal feed that bears or contains such drug) is subject to the following:

''(1) Each approval of the use of such drug in poultry is rescinded upon the expiration of the 180-day period beginning on such date of enactment unless, before the expiration of such period, the Secretary determines 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 use of such drug in poultry.

''(2) In carrying out paragraph (1), the Secretary may not consider any data regarding a fluoroquinolone that is submitted to the Secretary by the holder of the approved application unless such data has been submitted to FDA Docket No. 00N–1571. The preceding sentence may not be construed as requiring the Secretary to accept further submissions to such docket if the period designated by the Secretary for the receipt of such submissions has ended.''.

(d) DEFINITION OF NONTHERAPEUTIC USE.—Section 512 of the Federal Food, Drug, and Cosmetic Act,

as amended by subsection (c) of this section, is amended by adding at the end the following:

''(s) For purposes of this section, the term 'nontherapeutic use', with respect to an antimicrobial new animal drug, means any use of such drug in an animal in the absence of disease, including use for growth promotion, feed efficiency, or routine disease prevention.''.

○