

107TH CONGRESS
2^D 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.

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 “Preservation of Anti-
5 biotics for Human Treatment Act of 2002”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) Several antibiotics and classes of antibiotics,
2 particularly penicillins, tetracyclines, macrolides (in-
3 cluding but not limited to erythromycin and tylosin),
4 lincomycin, bacitracin, virginiamycin, amino-
5 glycosides, and sulfonamides, that either are used in
6 or are related to antibiotics used in humans to treat
7 infectious diseases are also routinely administered to
8 healthy agricultural animals, generally via feed or
9 water, in order to promote the animals' growth or to
10 prevent disease. Such uses do not require a veteri-
11 narian's prescription.

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

17 (3) In 1969, the Swann Committee was formed
18 in the United Kingdom to examine the public health
19 effects of use of antimicrobial drugs in food-pro-
20 ducing animals. The Committee recommended that
21 antimicrobials be divided into "feed" and "thera-
22 peutic" classes of drugs and that the "feed" class
23 not include drugs used therapeutically in humans or
24 animals. Most developed countries in the world, with
25 the exception of the United States and Canada, re-

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

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

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

15 (6) In December 1998, health ministers for the
16 European Union countries voted to ban the remain-
17 ing human-use antibiotics still in use to promote ani-
18 mal growth. The ban on using virginiamycin, tylosin,
19 spiramycin, and bacitracin in animal feed became ef-
20 fective for the 15 member states of the European
21 Union on July 1, 1999. Prior to that action, indi-
22 vidual European countries, including the United
23 Kingdom, Denmark, Finland, and Sweden, had
24 banned the use in animal feed of specific antibiotics.

1 (7) An April 1999 study by the General Ac-
2 counting Office concluded that resistant strains of
3 three microorganisms that cause foodborne illness or
4 disease in humans—salmonella, campylobacter, and
5 E. coli—are linked to the use of antibiotics in ani-
6 mals.

7 (8) In October 2000, the Food and Drug Ad-
8 ministration issued a notice announcing its intention
9 to withdraw approvals for use of fluoroquinolone
10 antibiotics in poultry, in light of the fact that in-
11 creased resistance to fluoroquinolones in certain bac-
12 teria followed approval of those antibiotics for such
13 use in the mid-1990s. While one company (Abbott
14 Laboratories) immediately agreed to voluntarily
15 withdraw its product, the only other manufacturer
16 (Bayer Corp.) is contesting FDA’s proposed with-
17 drawal and continues to market its product. Pre-
18 vious proceedings by FDA to withdraw approval of
19 animal drugs have taken substantial amounts of
20 time following initiation of formal action by FDA,
21 including 6 years in one instance and 20 in another.

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

1 (10) In June 2001, the American Medical Asso-
2 ciation adopted a resolution opposing nontherapeutic
3 use of antimicrobials in animal agriculture. Organi-
4 zations that have taken a similar position include
5 the American College of Preventive Medicine, the
6 American Public Health Association, and the Coun-
7 cil of State and Territorial Epidemiologists.

8 (11) In October 2001, the New England Jour-
9 nal of Medicine published a guest editorial titled
10 “Antimicrobials in Animal Feed—Time to Stop”.
11 The editorial urged a ban on nontherapeutic use in
12 animals of medically important antibiotics, and on
13 use in animals of fluoroquinolones.

14 (12) In January 2001, a Federal Interagency
15 Task Force released an Action Plan, which notes
16 that “drug-resistant pathogens are a growing men-
17 ace to all people, regardless of age, gender, or socio-
18 economic background. If we do not act to address
19 the problem... [d]rug choices for the treatment of
20 common infections will become increasingly limited
21 and expensive—and, in some cases, nonexistent.”.

22 (13) Scientific studies have shown that resist-
23 ance traits can be transferred among unrelated spe-
24 cies of bacteria, including from nonpathogens to
25 pathogens.

1 **SEC. 3. REQUIRING PROOF OF SAFETY OF ANTIMICROBIAL**
2 **NEW ANIMAL DRUGS.**

3 (a) NONTHERAPEUTIC USE; APPLICATIONS PENDING
4 ON OR SUBMITTED AFTER ENACTMENT.—Section
5 512(d)(1) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 360b(d)(1)) is amended—

7 (1) in subparagraph (H), by striking “or” at
8 the end;

9 (2) by redesignating subparagraph (I) as sub-
10 paragraph (J);

11 (3) by inserting after subparagraph (H) the fol-
12 lowing subparagraph:

13 “(I) such drug is an antimicrobial new animal
14 drug and the applicant has failed to demonstrate
15 that there is a reasonable certainty of no harm to
16 human health due to the development of anti-
17 microbial resistance that is attributable, in whole or
18 in part, to the nontherapeutic use of such drug; or”;
19 and

20 (4) in the matter after and below subparagraph
21 (J) (as redesignated by paragraph (2) of this sub-
22 section), by striking “(A) through (I)” and inserting
23 “(A) through (J)”.

24 (b) NONTHERAPEUTIC USE; RESCINDING OF AP-
25 PROVAL FOR CERTAIN CURRENTLY APPROVED DRUGS.—
26 Section 512 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 360b) is amended by adding at the end the
2 following subsection:

3 “(q) With respect to each antimicrobial new animal
4 drug for which, as of the day before the date of the enact-
5 ment of the Preservation of Antibiotics for Human Treat-
6 ment Act of 2002, there was in effect an approval of an
7 application filed pursuant to subsection (b), the approval
8 of a nontherapeutic use of such drug (including use
9 through animal feed that bears or contains such drug) is
10 subject to the following, as applicable:

11 “(1) In the case of penicillins, tetracyclines,
12 macrolides (including but not limited to erythro-
13 mycin and tylosin), lincomycin, bacitracin,
14 virginiamycin, aminoglycosides, and sulfonamides:

15 “(A) Each approval of a nontherapeutic
16 use of any of such drugs in an animal is re-
17 scinded upon the expiration of the two-year pe-
18 riod beginning on such date of enactment un-
19 less, before the expiration of such period, the
20 Secretary determines that the holder of the ap-
21 proved application has demonstrated that there
22 is a reasonable certainty of no harm to human
23 health due to the development of antimicrobial
24 resistance that is attributable, in whole or in
25 part, to the nontherapeutic use of such drug.

1 “(B) In carrying out subparagraph (A),
2 the Secretary may not consider any data re-
3 garding the antimicrobial new animal drug in-
4 volved that is submitted to the Secretary after
5 the expiration of the 180-day period beginning
6 on such date of enactment, unless such data
7 were not available for submission within such
8 180-day period.

9 “(C) If pursuant to subparagraph (A) the
10 Secretary determines, with respect to the anti-
11 microbial new animal drug involved, that there
12 is not a reasonable certainty of no harm to
13 human health, the Secretary may issue an order
14 withdrawing approval of such drug at any time
15 before the date on which the drug would be re-
16 scinded under such subparagraph.

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

19 “(A) If the Secretary grants an exemption
20 under section 505(i) regarding such a drug, or
21 a drug with substantially the same active ingre-
22 dients, each approval of a nontherapeutic use of
23 such new animal drug in an animal is rescinded
24 upon the expiration of the two-year period be-
25 ginning on the date on which the Secretary pro-

1 vides notice in accordance with subparagraph
2 (C) regarding the new animal drug, except as
3 provided in subparagraph (D). Such notice shall
4 be so provided not later than 10 days after the
5 date on which the Secretary grants the exemp-
6 tion under section 505(i).

7 “(B) If an application for such a drug, or
8 a drug with substantially the same active ingre-
9 dients, is submitted to the Secretary under sec-
10 tion 505(b) or under section 351 of the Public
11 Health Service Act, and the Secretary has not
12 previously granted an exemption under section
13 505(i) regarding the drug, each approval of a
14 nontherapeutic use of such new animal drug in
15 an animal is rescinded upon the expiration of
16 the two-year period beginning on the date on
17 which the Secretary provides notice in accord-
18 ance with subparagraph (C) regarding the new
19 animal drug, except as provided in subpara-
20 graph (D). Such notice shall be so provided not
21 later than 10 days after the date on which the
22 Secretary receives the application under section
23 505(b) or under such section 351, as the case
24 may be.

1 “(C) For purposes of subparagraph (A)
2 and (B), notice regarding the antimicrobial new
3 animal drug involved is provided in accordance
4 with this subparagraph if the Secretary informs
5 the holder of the approved application for the
6 nontherapeutic use of such drug, in writing, of
7 the applicability of this paragraph to such ap-
8 plication (including that approval of the appli-
9 cation will be rescinded, except as provided in
10 subparagraph (D), and including the oppor-
11 tunity under subparagraph (E) to submit data).

12 “(D) Subparagraph (A) or (B), as the case
13 may be, applies to the antimicrobial new animal
14 drug involved unless, before the date on which
15 approval would be rescinded under such sub-
16 paragraph, the Secretary determines that the
17 holder of the approved application has dem-
18 onstrated that there is a reasonable certainty of
19 no harm to human health due to the develop-
20 ment of antimicrobial resistance that is attrib-
21 utable, in whole or in part, to the nonthera-
22 peutic use of such drug.

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

1 involved that is submitted to the Secretary after
2 the expiration of the 180-day period beginning
3 on the date on which the Secretary provides no-
4 tice in accordance with subparagraph (C) to the
5 holder of the approved application for the non-
6 therapeutic use of such drug.

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

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

20 “(r) With respect to a fluoroquinolone for which, as
21 of the day before the date of the enactment of the Preser-
22 vation of Antibiotics for Human Treatment Act of 2002,
23 there was in effect an approval of an application filed pur-
24 suant to subsection (b), the use of such drug (including

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

3 “(1) Each approval of the use of such drug in
4 poultry is rescinded upon the expiration of the 180-
5 day period beginning on such date of enactment un-
6 less, before the expiration of such period, the Sec-
7 retary determines that the holder of the approved
8 application has demonstrated that there is a reason-
9 able certainty of no harm to human health due to
10 the development of antimicrobial resistance that is
11 attributable, in whole or in part, to the use of such
12 drug in poultry.

13 “(2) In carrying out paragraph (1), the Sec-
14 retary may not consider any data regarding a
15 fluoroquinolone that is submitted to the Secretary by
16 the holder of the approved application unless such
17 data has been submitted to FDA Docket No. 00N-
18 1571. The preceding sentence may not be construed
19 as requiring the Secretary to accept further submis-
20 sions to such docket if the period designated by the
21 Secretary for the receipt of such submissions has
22 ended.”.

23 (d) DEFINITION OF NONTHERAPEUTIC USE.—Sec-
24 tion 512 of the Federal Food, Drug, and Cosmetic Act,

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

3 “(s) For purposes of this section, the term ‘nonthera-
4 peutic use’, with respect to an antimicrobial new animal
5 drug, means any use of such drug in an animal in the
6 absence of disease, including use for growth promotion,
7 feed efficiency, or routine disease prevention.”.

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