

114TH CONGRESS
1ST SESSION

H. R. 2459

To amend the Federal Food, Drug, and Cosmetic Act to enhance the reporting requirements pertaining to use of antimicrobial drugs in food animals.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Ms. SLAUGHTER (for herself, Mr. TED LIEU of California, Mr. RANGEL, and Ms. SCHAKOWSKY) 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 enhance the reporting requirements pertaining to use of antimicrobial drugs in food animals.

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 “Delivering Anti-
5 microbial Transparency in Animals Act of 2015”.

6 **SEC. 2. PURPOSE.**

7 The purpose of this Act is to provide the Food and
8 Drug Administration and the public with better informa-

1 tion on the use of antimicrobial drugs in animals used for
2 food to—

3 (1) enable public health officials and scientists
4 to better understand and interpret trends and vari-
5 ations in rates of microbial resistance to such anti-
6 microbial drugs;

7 (2) improve the understanding of the relation-
8 ship between antimicrobial drug use in animals used
9 for food and antimicrobial drug resistance in mi-
10 crobes in and on animals and humans; and

11 (3) identify interventions to prevent and control
12 such antimicrobial drug resistance.

13 **SEC. 3. ENHANCED REPORTING REQUIREMENTS.**

14 (a) REPORTS.—Section 512(l) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 360b(l)) is amended
16 by striking paragraph (3) and inserting the following:

17 “(3)(A) In the case of each new animal drug
18 described in paragraph (1) that contains an anti-
19 microbial active ingredient, the sponsor of the drug
20 shall submit an annual report to the Secretary on
21 the amount of each antimicrobial active ingredient in
22 the drug that is sold or distributed for use in food-
23 producing animals, including information on any dis-
24 tributor-labeled product.

1 “(B) Each report under this paragraph shall
2 specify the amount of each antimicrobial active in-
3 gredient—

4 “(i) by container size, strength, and dosage
5 form;

6 “(ii) by quantities distributed to each State
7 domestically and by quantities exported; and

8 “(iii) by dosage form, including (for each
9 dosage form) the known or estimated amounts
10 of the antimicrobial active ingredient sold or
11 distributed for use in each food-producing ani-
12 mal for which the new animal drug is approved,
13 including a description of the methods used to
14 determine or estimate the amounts.

15 “(4)(A) Subject to subparagraph (B), in the
16 case of animal feed in final formulation bearing or
17 containing a new animal drug for which reporting is
18 required under paragraph (3), a live poultry dealer,
19 swine contractor, or feed lot operator who purchases,
20 contracts, or manufactures such feed shall submit to
21 the Secretary an annual report that specifies, by
22 food-producing animal for which the new animal
23 drug is approved and, where applicable as deter-
24 mined by the Secretary, by production class of such
25 animal—

1 “(i) the amount of each antimicrobial ac-
2 tive ingredient contained per kilogram of each
3 such feed sold or distributed for that animal
4 and, where applicable, production class;

5 “(ii) the quantity of such feed sold or dis-
6 tributed for that animal and, where applicable,
7 production class; and

8 “(iii) for each such feed sold or distributed
9 under a veterinary feed directive—

10 “(I) the indications for which the feed
11 was sold or distributed and the quantities
12 of such feed that were sold or distributed
13 per each such indication;

14 “(II) the number of individuals of the
15 food-producing animal and, where applica-
16 ble, the production class to which the feed
17 was intended; and

18 “(III) the length of time over which
19 the feed was intended to be provided to the
20 animals and the dose of the active anti-
21 microbial ingredient the animals were in-
22 tended to receive.

23 “(B)(i) Subparagraph (A) does not apply to a
24 live poultry dealer, swine contractor, or feed lot op-
25 erator if the total value of the live animals owned,

1 purchased, sold, contracted for, or otherwise con-
2 trolled by the dealer, contractor, or operator, directly
3 or through subsidiaries or affiliates, per year, does
4 not exceed—

5 “(I) \$10,000,000; or

6 “(II) such other sum as the Secretary may
7 specify through regulation.

8 “(ii) The Secretary may specify through regula-
9 tion alternative reporting requirements, including via
10 pilot programs or based on the results of pilot pro-
11 grams—

12 “(I) to improve the accuracy of reports;

13 “(II) to lessen the burden of reporting;

14 “(III) to facilitate the Secretary’s ability to
15 provide public summaries of the reports; or

16 “(IV) to improve the Secretary’s ability to
17 use the reports, or the public’s ability to use the
18 summaries under paragraph (5), to understand
19 the relationship between sales, distribution, and
20 end-use practices with respect to feed con-
21 taining new animal drugs described in para-
22 graph (1) and antimicrobial resistance trends in
23 microbes in animals, animal food products, and
24 humans.

1 “(5)(A) Each report under paragraph (3) or (4)
2 shall—

3 “(i) be submitted electronically not later
4 than March 31 each year;

5 “(ii) cover the period of the preceding cal-
6 endar year;

7 “(iii) include separate information for each
8 month of such calendar year; and

9 “(iv) be in such format as the Secretary
10 may require.

11 “(B) In specifying a format under subpara-
12 graph (A)(iv), the Secretary shall seek to ensure
13 that such format enables the data reported to be in-
14 tegrated or otherwise easily associated and compared
15 with data from other Federal databases containing
16 data on—

17 “(i) drug sales for human use; and

18 “(ii) rates of antimicrobial resistance in
19 bacteria in and on animals, animal food prod-
20 ucts, and people.

21 “(C) The Secretary may share information re-
22 ported under paragraph (3) or (4) with the Anti-
23 microbial Resistance Task Force established under
24 section 319E of the Public Health Service Act.

1 “(D)(i) Not later than November 30 each year,
2 the Secretary shall make publicly available sum-
3 maries of the information reported under paragraphs
4 (3) and (4).

5 “(ii) For each summary under clause (i), except
6 as provided in clause (iii), the Secretary shall—

7 “(I) report data by antimicrobial drug
8 class;

9 “(II) for each such antimicrobial drug
10 class, specify—

11 “(aa) the quantity of drugs sold or
12 distributed per dosage form;

13 “(bb) the percentage of drugs sold or
14 distributed with labeled indications that
15 fall within each of the following categories:
16 growth promotion, feed efficiency, or other
17 production purposes; disease prevention;
18 disease control; and disease treatment;

19 “(cc) the quantity of drugs sold or
20 distributed per each of the following mar-
21 keting categories: over-the-counter, pre-
22 scription, and veterinary feed directive;

23 “(dd) the quantity of drugs sold or
24 distributed per State of sale or distribu-
25 tion; and

1 “(ee) the known or estimated quantity
2 of drugs sold or distributed for each food-
3 producing animal and, where feasible, pro-
4 duction class of such animal; and

5 “(III) for each feed sold or distributed
6 under a veterinary food directive for which re-
7 porting is required under paragraph (4), in-
8 clude the information reported pursuant to sub-
9 clauses (I), (II), and (III) of paragraph
10 (4)(A)(iii).

11 “(iii) For any antimicrobial drug class with
12 fewer than 3 sponsors of approved new animal
13 drugs, instead of reporting data under clause (ii),
14 the Secretary shall for each such class—

15 “(I) report data by category of importance
16 of the antimicrobial drugs within that class to
17 human medicine, as determined by the Sec-
18 retary; and

19 “(II) to the extent feasible for each such
20 category, specify—

21 “(aa) the quantity of drugs sold or
22 distributed per dosage form;

23 “(bb) the percentage of drugs sold or
24 distributed with labeled indications that
25 fall within each of the following categories:

1 growth promotion, feed efficiency, or other
2 production purposes; disease prevention;
3 disease control; and disease treatment;

4 “(cc) the quantity of drugs sold or
5 distributed per each of the following mar-
6 keting categories: over-the-counter, pre-
7 scription, and veterinary feed directive; and

8 “(dd) the quantity of drugs sold or
9 distributed per State of sale or distribu-
10 tion.

11 “(iv) In carrying out this subparagraph, the
12 Secretary shall report data in a manner consistent
13 with protecting both national security and confiden-
14 tial business information.

15 “(E) In this paragraph, the terms ‘live poultry
16 dealer’ and ‘swine contractor’ have the meanings
17 given to those terms in section 2 of the Packers and
18 Stockyards Act, 1921.”.

19 (b) RULE OF APPLICATION.—The amendment made
20 by this section applies to reports under paragraphs (3)
21 and (4) of section 512(l) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 360b(l)) (as amended by sub-
23 section (a)) that cover the period of the first calendar year
24 beginning after the date of enactment of this Act or any
25 subsequent calendar year. The provisions of section

1 512(l)(3) of such Act, as in effect the day before the date
2 of enactment of this Act, apply to reports that cover the
3 period of any calendar year beginning before the calendar
4 years described in the preceding sentence.

5 **SEC. 4. ENHANCED COLLABORATION BETWEEN THE FOOD**
6 **AND DRUG ADMINISTRATION AND THE DE-**
7 **PARTMENT OF AGRICULTURE.**

8 The Secretary of Health and Human Services, acting
9 through the Commissioner of Food and Drugs, shall in-
10 crease collaboration and coordination with the Secretary
11 of Agriculture to expand and coordinate the collection of
12 data on the use of antimicrobial drugs in or on cattle,
13 swine, chickens, turkeys, and such other food-producing
14 animal species as agreed to by the Secretary of Health
15 and Human Services and the Secretary of Agriculture, in-
16 cluding by providing information to the Secretary of Agri-
17 culture for use by—

- 18 (1) the Animal and Plant Health Inspection
19 Service to help inform its collection of data through
20 the National Animal Health Monitoring System; and
21 (2) the Economic Research Service to help in-
22 form its collection of data through the Agricultural
23 Resource Management Survey.

1 **SEC. 5. REPORT BY GAO.**

2 (a) IN GENERAL.—Not later than 3 years after the
3 date of enactment of this Act, the Comptroller General
4 of the United States shall commence a study to evaluate—

5 (1) the voluntary approach used by the Food
6 and Drug Administration to eliminate injudicious
7 use of antimicrobial drugs in food-producing ani-
8 mals; and

9 (2) the effectiveness of the data collection ac-
10 tivities conducted by the Food and Drug Adminis-
11 tration regarding antimicrobial resistance.

12 (b) REPORT.—Not later than 1 year after com-
13 mencing the study required by subsection (a), the Comp-
14 troller General of the United States shall submit to the
15 Committee on Health, Education, Labor, and Pensions of
16 the Senate and the Committee on Energy and Commerce
17 of the House of Representatives a report that describes
18 the results of such study.

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