

113TH CONGRESS
1ST SESSION

H. R. 820

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

FEBRUARY 26, 2013

Mr. WAXMAN (for himself 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 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 2013”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

8 (1) Antimicrobials are of critical importance to
9 public health and to the American economy.

1 (2) Use of antimicrobials, whether in human
2 medicine or in agriculture, contributes to the devel-
3 opment and spread of antimicrobial resistance.

4 (3) Data from the Food and Drug Administra-
5 tion (FDA) indicate that approximately 80 percent
6 of all antimicrobials sold in the United States, over
7 29,000,000 pounds in 2009, were sold for use in
8 food animals.

9 (4) A study published in September, 2012, in
10 Proceedings of the National Academy of Sciences of
11 the United States of America found that even low
12 doses of antimicrobials in animal feed for short peri-
13 ods of time increased the prevalence of the bacteria
14 E. coli and the prevalence and diversity of anti-
15 microbial resistance genes in bacteria in pigs.

16 (5) Public Law 110–316, the Animal Drug
17 User Fee Amendments of 2008, requires producers
18 of drugs used in food animals to provide specified in-
19 formation annually to the FDA on the sales and in-
20 dications for use of such drugs.

21 (6) A September 2011 study by the Govern-
22 ment Accountability Office found that the data pro-
23 vided to the FDA under the Animal Drug User Fee
24 Amendments Act of 2008 lacked sufficient details
25 necessary to analyze trends in antimicrobial resist-

1 ance, such as information on actual drug use in spe-
2 cific food-producing animal species.

3 **SEC. 3. PURPOSE.**

4 The purpose of this Act is to provide the Food and
5 Drug Administration and the public with better informa-
6 tion on the use of antimicrobial drugs in animals used for
7 food to—

8 (1) enable public health officials and scientists
9 to better understand and interpret trends and vari-
10 ations in rates of microbial resistance to such anti-
11 microbial drugs;

12 (2) improve the understanding of the relation-
13 ship between antimicrobial drug use in animals used
14 for food and antimicrobial drug resistance in mi-
15 crobes in and on animals and humans; and

16 (3) identify interventions to prevent and control
17 such antimicrobial drug resistance.

18 **SEC. 4. ENHANCED REPORTING REQUIREMENTS.**

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

22 “(3)(A) In the case of each new animal drug
23 described in paragraph (1) that contains an anti-
24 microbial active ingredient, the sponsor of the drug
25 shall submit an annual report to the Secretary on

1 the amount of each antimicrobial active ingredient in
2 the drug that is sold or distributed for use in food-
3 producing animals, including information on any dis-
4 tributor-labeled product.

5 “(B) Each report under this paragraph shall
6 specify the amount of each antimicrobial active in-
7 gredient—

8 “(i) by container size, strength, and dosage
9 form;

10 “(ii) by quantities distributed to each State
11 domestically and by quantities exported; and

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

19 “(4)(A) Subject to subparagraph (B), in the
20 case of animal feed in final formulation bearing or
21 containing a new animal drug for which reporting is
22 required under paragraph (3), a live poultry dealer,
23 swine contractor, or feed lot operator who purchases,
24 contracts, or manufactures such feed shall submit to
25 the Secretary an annual report that specifies, by

1 food-producing animal for which the new animal
2 drug is approved and, where applicable as deter-
3 mined by the Secretary, by production class of such
4 animal—

5 “(i) the amount of each antimicrobial ac-
6 tive ingredient contained per kilogram of each
7 such feed sold or distributed for that animal
8 and, where applicable, production class;

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

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

14 “(I) the indications for which the feed
15 was sold or distributed and the quantities
16 of such feed that were sold or distributed
17 per each such indication;

18 “(II) the number of individuals of the
19 food-producing animal and, where applica-
20 ble, the production class to which the feed
21 was intended; and

22 “(III) the length of time over which
23 the feed was intended to be provided to the
24 animals and the dose of the active anti-

1 microbial ingredient the animals were in-
2 tended to receive.

3 “(B)(i) Subparagraph (A) does not apply to a
4 live poultry dealer, swine contractor, or feed lot op-
5 erator if the total value of the live animals owned,
6 purchased, sold, contracted for, or otherwise con-
7 trolled by the dealer, contractor, or operator, directly
8 or through subsidiaries or affiliates, per year, does
9 not exceed—

10 “(I) \$10,000,000; or

11 “(II) such other sum as the Secretary may
12 specify through regulation.

13 “(ii) The Secretary may specify through regula-
14 tion alternative reporting requirements, including via
15 pilot programs or based on the results of pilot pro-
16 grams—

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

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

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

21 “(IV) to improve the Secretary’s ability to
22 use the reports, or the public’s ability to use the
23 summaries under paragraph (5), to understand
24 the relationship between sales, distribution, and
25 end-use practices with respect to feed con-

1 taining new animal drugs described in para-
2 graph (1) and antimicrobial resistance trends in
3 microbes in animals, animal food products, and
4 humans.

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

7 “(i) be submitted electronically not later
8 than March 31 each year;

9 “(ii) cover the period of the preceding cal-
10 endar year;

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

13 “(iv) be in such format as the Secretary
14 may require.

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

21 “(i) drug sales for human use; and

22 “(ii) rates of antimicrobial resistance in
23 bacteria in and on animals, animal food prod-
24 ucts, and people.

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

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

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

11 “(I) report data by antimicrobial drug
12 class;

13 “(II) for each such antimicrobial drug
14 class, specify—

15 “(aa) the quantity of drugs sold or
16 distributed per dosage form;

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

23 “(cc) the quantity of drugs sold or
24 distributed per each of the following mar-

1 keting categories: over-the-counter, pre-
2 scription, and veterinary feed directive;

3 “*(dd)* the quantity of drugs sold or
4 distributed per State of sale or distribu-
5 tion; and

6 “*(ee)* the known or estimated quantity
7 of drugs sold or distributed for each food-
8 producing animal and, where feasible, pro-
9 duction class of such animal; and

10 “*(III)* for each feed sold or distributed
11 under a veterinary food directive for which re-
12 porting is required under paragraph (4), in-
13 clude the information reported pursuant to sub-
14 clauses (I), (II), and (III) of paragraph
15 (4)(A)(iii).

16 “*(iii)* For any antimicrobial drug class with
17 fewer than 3 sponsors of approved new animal
18 drugs, instead of reporting data under clause (ii),
19 the Secretary shall for each such class—

20 “*(I)* report data by category of importance
21 of the antimicrobial drugs within that class to
22 human medicine, as determined by the Sec-
23 retary; and

24 “*(II)* to the extent feasible for each such
25 category, specify—

1 “(aa) the quantity of drugs sold or
2 distributed per dosage form;

3 “(bb) the percentage of drugs sold or
4 distributed with labeled indications that
5 fall within each of the following categories:
6 growth promotion, feed efficiency, or other
7 production purposes; disease prevention;
8 disease control; and disease treatment;

9 “(cc) the quantity of drugs sold or
10 distributed per each of the following mar-
11 keting categories: over-the-counter, pre-
12 scription, and veterinary feed directive; and

13 “(dd) the quantity of drugs sold or
14 distributed per State of sale or distribu-
15 tion.

16 “(iv) In carrying out this subparagraph, the
17 Secretary shall report data in a manner consistent
18 with protecting both national security and confiden-
19 tial business information.

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

24 (b) RULE OF APPLICATION.—The amendment made
25 by this section applies to reports under paragraphs (3)

1 and (4) of section 512(l) of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 360b(l)) (as amended by sub-
3 section (a)) that cover the period of calendar year 2014
4 or any subsequent calendar year. The provisions of section
5 512(l)(3) of such Act, as in effect the day before the date
6 of enactment of this Act, apply to reports that cover the
7 period of calendar year 2013.

8 **SEC. 5. ENHANCED COLLABORATION BETWEEN THE FOOD**
9 **AND DRUG ADMINISTRATION AND THE DE-**
10 **PARTMENT OF AGRICULTURE.**

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

21 (1) the Animal and Plant Health Inspection
22 Service to help inform its collection of data through
23 the National Animal Health Monitoring System; and

1 (2) the Economic Research Service to help in-
2 form its collection of data through the Agricultural
3 Resource Management Survey.

4 **SEC. 6. ACTION BY GOVERNMENT ACCOUNTABILITY OF-**
5 **FICE.**

6 (a) PUBLICATION OF FINAL GUIDANCE.—Not later
7 than 180 days after the date of enactment of this Act,
8 the Secretary of Health and Human Services shall publish
9 a final version of draft guidance #213, entitled “New Ani-
10 mal Drugs and New Animal Drug Combination Products
11 Administered in or on Medicated Feed or Drinking Water
12 of Food-Producing Animals: Recommendations for Drug
13 Sponsors for Voluntarily Aligning Product Use Conditions
14 with GFI #209”.

15 (b) REPORT BY GAO.—

16 (1) IN GENERAL.—Not later than 3 years after
17 the publication of final guidance pursuant to sub-
18 section (a), the Comptroller General of the United
19 States shall commence a study to evaluate—

20 (A) the voluntary approach used by the
21 Food and Drug Administration to eliminate in-
22 judicious use of antimicrobial drugs in food-pro-
23 ducing animals; and

1 (B) the effectiveness of the data collection
2 activities conducted by the Food and Drug Ad-
3 ministration regarding antimicrobial resistance.

4 (2) REPORT.—Not later than 1 year after com-
5 mencing the study required by paragraph (1), the
6 Comptroller General of the United States shall sub-
7 mit to the Committee on Health, Education, Labor,
8 and Pensions of the Senate and the Committee on
9 Energy and Commerce of the House of Representa-
10 tives a report that describes the results of such
11 study.

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