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(Original Signature of Member)

113TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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

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IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

\_\_\_\_\_  
**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:

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

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

6           (3) Data from the Food and Drug Administra-  
7 tion (FDA) indicate that approximately 80 percent  
8 of all antimicrobials sold in the United States, over  
9 29,000,000 pounds in 2009, were sold for use in  
10 food animals.

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

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

23           (6) A September 2011 study by the Govern-  
24 ment Accountability Office found that the data pro-  
25 vided to the FDA under the Animal Drug User Fee

1 Amendments Act of 2008 lacked sufficient details  
2 necessary to analyze trends in antimicrobial resist-  
3 ance, such as information on actual drug use in spe-  
4 cific food-producing animal species.

5 **SEC. 3. PURPOSE.**

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

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

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

18 (3) identify interventions to prevent and control  
19 such antimicrobial drug resistance.

20 **SEC. 4. ENHANCED REPORTING REQUIREMENTS.**

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

24 “(3)(A) In the case of each new animal drug  
25 described in paragraph (1) that contains an anti-

1 microbial active ingredient, the sponsor of the drug  
2 shall submit an annual report to the Secretary on  
3 the amount of each antimicrobial active ingredient in  
4 the drug that is sold or distributed for use in food-  
5 producing animals, including information on any dis-  
6 tributor-labeled product.

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

10 “(i) by container size, strength, and dosage  
11 form;

12 “(ii) by quantities distributed to each State  
13 domestically and by quantities exported; and

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

21 “(4)(A) Subject to subparagraph (B), in the  
22 case of animal feed in final formulation bearing or  
23 containing a new animal drug for which reporting is  
24 required under paragraph (3), a live poultry dealer,  
25 swine contractor, or feed lot operator who purchases,

1 contracts, or manufactures such feed shall submit to  
2 the Secretary an annual report that specifies, by  
3 food-producing animal for which the new animal  
4 drug is approved and, where applicable as deter-  
5 mined by the Secretary, by production class of such  
6 animal—

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

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

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

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

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

24 “(III) the length of time over which  
25 the feed was intended to be provided to the

1 animals and the dose of the active anti-  
2 microbial ingredient the animals were in-  
3 tended to receive.

4 “(B)(i) Subparagraph (A) does not apply to a  
5 live poultry dealer, swine contractor, or feed lot op-  
6 erator that does not own, buy, sell, contract with, or  
7 otherwise control, directly or through subsidiaries or  
8 affiliates, animals or animal products per year, the  
9 total value of which is not less than—

10 “(I) \$1,000,000; 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.