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August 18, 2015

*SUBMITTED ELECTRONICALLY*

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2012-N-0447, Proposed Rule: Antimicrobial Animal Sales and Distribution Reporting**

To Whom It May Concern:

The National Chicken Council (NCC) represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States. NCC and its members are committed to the judicious use and continued efficacy of antibiotics for human and broiler health. NCC has collaborated with the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) to identify methods through which the industry can help in reducing the spread of antimicrobial-resistant bacteria and is fully supportive of Guidance for Industry (GFI) #209 and #213, as well as the Veterinary Feed Directive (VFD). We appreciate the opportunity to provide comment on *Docket No. FDA-2012-N-0447* and would like to take the opportunity to express a number of concerns regarding the proposed rule.

In accordance with Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA), FDA has been collecting antimicrobial new animal drug sales data and issuing a Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals (the Report) with its findings. The Report is widely referenced domestically and internationally as an indication of antibiotic use in United States agricultural animal production, and therefore any changes to Report or the underlying Data could have significant repercussions for the understanding and conversation about the distribution of antimicrobial new animal drugs. The current proposed rule would increase the scope of the Report by requiring animal drug sponsors to submit species-specific estimates of product sales as a percentage of total sales broken down into the following categories: cattle, swine, chickens, turkeys, and "other species/unknown".<sup>1</sup>

NCC believes that FDA's current data collection and reporting program meets the ADUFA requirements. Accordingly, before making any changes to the data collection or reporting program, we recommend FDA carefully evaluate whether the changes would promote public

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<sup>1</sup> Docket No. FDA-2012-N-0447. Antimicrobial Animal Drug Sales and Distribution Reporting.

understanding in a meaningful and accurate way and whether focusing these resources on other programs would have a more significant effect. NCC supports the judicious use in food producing animals of antimicrobials that are medically important for humans; however, we do not believe that the proposed changes will further that objective, especially when compared to alternative programs that may be more effective.

### **Species-Specific Estimates Are Highly Susceptible to Misinterpretation**

NCC is concerned about the potential for species-specific sales and distribution information to inaccurately degrade the public's perception of animal production agriculture. Statistics from the Report may be misinterpreted or misrepresented, resulting in a skewed understanding of judicious use of antimicrobials. This possibility is recognized in the most recent Report, which cautions that there are "inherent limitations on how the data provided in this report may appropriately be interpreted and used".<sup>2</sup> Administration of population medicine is critical to maintaining the health and welfare of the country's agricultural animals and requires treatment on a large scale. Treatment and dosage are influenced by a number of factors—including the age, sex, and production method for the given animal, weather, geographic location, and disease events—many of which are not fully under the farmer's control. Such circumstances may necessitate increased use of antimicrobials in the interest of the animals' welfare but could negatively skew the information reported in FDA's annual report by suggesting increased sales of antimicrobials for a given class of animals.

The necessary reliance on estimates further clouds the information provided by the proposed sales and distribution. These estimates will be inherently imprecise but will likely be interpreted as though they were exact measures of antibiotic use. Many antimicrobial products are approved for use in multiple species (e.g., turkeys, broiler chickens, and laying hens), and antimicrobials produced with one species in mind could ultimately be destined for another. Unavoidable limits to knowledge of final product distribution in one species versus another will result in rough guesses being widely accepted as precise usage.

Compounding these concerns, the release of sales and distribution data by animal species poses the potential to distort the marketplace for agricultural products due to public perception of animal care. NCC represents members following a spectrum of production practices regarding antibiotic use, each of which represent best practices for broiler health and welfare as outlined by *The National Chicken Council's Animal Welfare Guidelines*. Animal welfare best practices and judicious antimicrobial use are similarly followed for other production animal species. NCC strongly believes that the publication of species-specific sales and distribution data may lead the public to perceive that one animal production class has better welfare practices or is safer to eat based on a lower volume of antimicrobials sold and distributed, without accounting for differences in medical treatment, administration, and actual usage. Such a scenario would result

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<sup>2</sup> 2013 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. 2015. Food and Drug Administration-Department of Health and Human Services.

in an unfounded bias among consumers, and therefore an unjust competitive advantage. This bias has the potential to negatively impact all classes of production animals dependent on the previous year's report, and lead to unnecessary public concern and confusion.

### **The Data Collected Reflect Sales, Not Use**

When considering the value of estimates of product sales and distribution of antimicrobial medications, it is important to note that the most recent 2013 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals states that the data submitted is “not indicative of how these antimicrobial drugs were actually used in animals”.<sup>3</sup> Given that the data collected does not give insight into the responsible use of the antimicrobial drugs in production animals, there is confusion as to how collecting species-specific distribution information would be consistent with the recommendations of Guidance for Industry #209.<sup>4</sup> On the contrary, this data would not provide information regarding the therapeutic use of an antimicrobial drug or evidence of veterinary oversight. The broiler chicken industry supports the removal of medically-important antimicrobial drugs for growth-promotion purposes, and has taken initiatives to investigate antimicrobial alternatives. These proactive measures have high potential to be overshadowed by imprecise sales and distribution data. We are also concerned that species-specific data will not further public health initiatives, slow antimicrobial resistance, or improve data collected through the National Antimicrobial Resistance Monitoring System (NARMS) program.

### **Agency Resources Are Better Deployed Through Alternative Programs**

The broiler chicken industry considers maintaining the efficacy of antibiotics for human use a top priority, and thus encourages federal oversight and data collection to focus on measurable public health parameters. The NARMS model of data collection has yielded information on the prevalence of bacterial isolates on retail meat and trends in antibiotic resistance of those isolates, specifically for serotypes of *Salmonella*, *Campylobacter*, *Enterococcus* and *Escherichia coli*. Observing trends of microbial presence and antimicrobial resistant strains on retail meat has a direct public health impact, as it indicates which isolates are potentially of higher concern to human health, and which antimicrobials have decreased activity against foodborne bacteria. In reviewing the most recent NARMS data, positive trends were observed including a decrease from 38% in 2009 to 20% in 2013 of resistance in *Salmonella* to cephalosporins; sustained susceptibility of *Salmonella* to ciprofloxacin and azithromycin; and a decline in multi-drug resistant *Salmonella* poultry isolates between 2011 and 2013.<sup>5</sup> These improvements occurred

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<sup>3</sup> 2013 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. 2015. Food and Drug Administration-Department of Health and Human Services.

<sup>4</sup> Guidance for Industry #209. The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals. 2012. Food and Drug Administration-Center for Veterinary Medicine.

<sup>5</sup> 2013 Retail Meat Report. National Antimicrobial Resistance Monitoring System. 2015. Food and Drug Administration-Center for Veterinary Medicine.

even as FDA has reported that the domestic sales and distribution of medically important antimicrobials used in food-production animals increased by 20% from 2009 to 2013.<sup>6</sup> It is evident that the collection of data on the sales and distribution of antimicrobials for use in food-production animals cannot be used for correlation to trends in bacterial presence and antimicrobial resistance. If that were the case, we would expect to see increased rates of antimicrobial resistant bacteria on retail meat samples, when in fact this has not occurred. With this in consideration, NCC respectfully suggests that resources instead be allocated to further strengthening the NARMS retail meat monitoring and USDA's National Animal Health Monitoring System (NAHMS) programs. Both programs provide quantified information on antimicrobial resistance and microbial frequency trends and result in direct public health improvement through monitoring microbes of interest and educating consumers of the importance of safe food handling techniques. Information from both the NARMS and NAHMS programs provides a clearer picture of changes in antimicrobial resistance, rather than on an imprecise estimate as provided by antimicrobial sales data.

## **Conclusion**

The National Chicken Council supports the efforts of the USDA and FDA to monitor antimicrobial resistance and their work with the agricultural community to discuss methods of judicious use and stewardship. Research initiatives such as the NARMS and NAHMS reports provide valuable information to the public, as well as to broiler chicken producers. The continued reliance on antimicrobial sales and distribution data unfortunately dilutes and distorts the information provided by NARMS and NAHMS, and NCC believes that the collection of species-specific data would contribute to consumer confusion and negative perception regarding agricultural animal production without providing a public health benefit.

The National Chicken Council appreciates the opportunity to provide comment. If you have questions regarding the above comments, please feel free to contact me. Thank you for your consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ashley B. Peterson". The signature is fluid and cursive, with the first name "Ashley" being more prominent and the last name "Peterson" written in a more compact, stylized manner.

Ashley B. Peterson, Ph.D.  
Senior Vice President, Scientific and Regulatory Affairs  
National Chicken Council

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<sup>6</sup> 2013 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. 2015. Food and Drug Administration-Department of Health and Human Services.