National Milk Producers Federation

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November 13, 2017

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

Re: Docket ID: FDA- 2017-N-1197-0002; The Food and Drug Administration' sProposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals Using a Biomass Denominator

To Whom It May Concern:

The National Milk Producers Federation (**NMPF**), established in 1916 and based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies.

Among the measures available to treat and prevent the outbreak and spread of animal diseases among the nation's dairy cattle, the judicious and responsible use of antimicrobial drugs has a positive impact on animal health and well-being while maintaining a safe milk supply for the public. Therefore, NMPF takes great interest in the Food and Drug Administration's (FDA) *Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals Using a Biomass Denominator* (FDA- 2017-N-1197-0002).

For nearly 30 years, the U.S. dairy industry has focused educational efforts on the judicious and responsible use of antimicrobial drugs through the annual publication of a Best Practices Manual. The 2017 edition of the National Dairy FARM Program: Farmers Assuring Responsible Management™ *Milk and Dairy Beef Drug Residue Prevention Manual* (published April 2017) developed by NMPF is the primary educational tool for dairy farm managers throughout the country on the judicious and responsible use of antibiotics including avoidance of drug residues in milk and meat. The 2017 edition of the Residue Prevention Manual also provides dairy farm managers guidance about the implementation of the Food and Drug Administration Guidance for Industry (GFI) #209 and #213 and the revised Veterinary Feed Directive (VFD) Rule.

Antimicrobial Data Collection Goals
NMPF supports the efforts of the FDA, the U.S. Department of Agriculture (USDA), and Centers for Disease Control and Prevention (CDC) to engage stakeholders for

feedback on the best approaches for data collection about antimicrobial use and potential resistance in food-producing animals. We have previously commented on our support for the FDA's GFI #209 & #213 and VFD rule which collectively limit the use of medically important antimicrobials to therapeutic purposes in livestock. Therapeutic uses include disease treatment, control, and prevention.

Assessing the impact of GFI #209 & #213 and the VFD rule will be difficult due to external drivers of bacterial resistance, the inherent unpredictability of bacterial mutation, and the length of time needed to assess change. As such, NMPF urges caution that data collection cannot simply be used to evaluate whether the GFIs and the VFD rule are having a "desired effect" on antibiotic use practices and antimicrobial resistance. Without careful definition, "desired effect" could easily be viewed as simply decreasing antimicrobial use in livestock without any discernible impact on resistance. A goal of merely decreasing antimicrobial use would be not only medically unreasonable, but also dangerous for animal health and wellbeing, as it cannot be guaranteed that rates of resistance will drop. The relationship between antibiotic use and resistance is highly complex with multiple factors extending beyond antibiotic use in food-producing animals, and associated data has strong potential to be misinterpreted to portray responsible husbandry practices as harmful, especially if bacterial resistance were not to decrease. These factors contribute to our concern that collecting antimicrobial use data without first outlining science-based goals and objectives may lead to less robust, less useful results.

NAHMS Data Collection

We agree that use and resistance data has value, as do data from other settings such as healthcare facilities, to monitor the landscape of antimicrobial resistance in these environments. Such data provides important information to help protect current and future populations in farm or healthcare settings. Monitoring of antimicrobial resistance on farms has been explored in the past through the National Animal Health Monitoring System (NAHMS), and we remain supportive of this voluntary and confidential sampling method. We also agree that data on animal demographics and health is needed; NAHMS additionally surveys data on existing animal diseases, while academic researchers and the World Organization for Animal Health (OIE) provide excellent monitoring of both existing and emerging diseases.

NMPF would like to see FDA expand efforts to collect on-farm antibiotic use data in cooperation with USDA. NMPF and numerous animal agriculture organizations have supported increased Congressional funding for this type of data collection, which was realized in the appropriation of $7 million to USDA in the FY 2017 Continuing Resolution for on-farm surveillance, data collection, sampling and testing to enhance the understanding of antibiotic use. We urge FDA to assist USDA in effectively utilizing these funds.

One Health Goal for Data Collection

The above-listed objectives are supported by NMPF because they point to meaningful health outcomes for both animals and humans; however, we must emphatically state that we are not supportive of collecting data on antibiotic sales or distribution. It has been acknowledged that antibiotic sales and distribution data does not yield information on how or why the antimicrobials have been used. Estimating aggregated species-specific sales and distribution data has not alleviated this problem; rather it continues to foster an inaccurate perception of animal production agriculture without accounting for a host of factors contributing to treatment. Such factors are varied and can include age, sex, and production method for the given animal; weather; geographic location; and disease events. Many of these factors are outside of both the farmers' and the companies' control. This has led to erroneous comparisons and misuse of the information as to the actual amounts and kinds of antibiotics used for people versus animals.

While FDA has attempted to caution about using data for these comparisons to make critical judgements on antibiotic use, misinformation and exaggerated claims are still reported in both print and social media. The reporting of sales and distribution by the agency has led to the misrepresentation of actual antimicrobial use in food animals by organizations who continue to promote the message that antibiotics are over used in agriculture. Despite the FDA release of commercially collected data on human sales in 2011 showing the distinct differences between animals and humans in shared medically important antimicrobial classes, these misrepresentations continue to appear in public statements and media reports. While, the utilization of the biomass denominator may allow FDA to put food animal antimicrobial sales volumes into better context, it is not a surrogate for actual on-farm use. We continue to believe that species estimates are non-scientific and only a best guess by the numerous pharmaceutical sponsors of these products. Further manipulation of the data based on these estimates can only further dilute the scientific validity of the results.

Biomass Denominator Manipulation

Upon review, NMPF cannot support the FDA *Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals Using a Biomass Denominator* (FDA- 2017-N-1197-0002) due to multiple reasons:

(1) Most veterinary antimicrobial products are approved for use in multiple species, multiple classes within a major food producing species, and, for multiple claims or indications. For example, a product may have approvals in poultry, swine and cattle. Within cattle there may be separate indications for veal calves, beef cattle, and dairy cattle, including separate claims for lactating and dry dairy cows with separate indications for each. With this complexity, the estimate of the number of animals and an appropriate weight of each class of animals is essential for the determination of a viable biomass denominator. ***NMPF believes biomass estimates***

by species will not provide the precision and accuracy necessary to provide useful data.

(2) When antimicrobial sales, or use, are reported based only on weight (e.g. mg/TAB) that data is not adjusted for potency. While this proposal attempts to adjust sales based on the weight of potentially treated animals (biomass or TAB), it overlooks the potency of various antimicrobials that may be used. A mg of a critically important drug is much more potent, and would treat many more animals, than a mg of an older drug such as tetracycline. ***NMPF believes that publication of these types of estimates will result in a push to reduce total species mg/TAB running the risk of pushing sales of more potent drugs (which are often ranked as critically important) rather than older, less important drugs.***

(3) NMPF is concerned that this proposal will lead to misuse of the reported mg/TAB data with attempts to compare one species data to another. Many factors make these comparisons inaccurate and counter-productive. For example, it takes approximately six weeks for a broiler to reach market weight while a dairy cow has a productive lifespan of 5.5 years. The potential for antimicrobials to be needed rises with life span, thus comparing a mg/TAB for a six-week-old bird to that of a 5.5-year-old dairy cow is nonsensical. ***NMPF believes we need to work together to preserve antimicrobials for human and animal health, and potentially pitting one animal protein commodity against another will not promote antimicrobial stewardship.***

(4) NMPF is concerned that this proposal will lead to misuse of the reported mg/TAB data with attempts to compare one country to another. Just as we have seen with ADD calculations in European countries the mg/TAB calculations will not be comparable from country to country. For example, ionophores (an animal only antibiotic) are currently reported in sales and distribution data in the U.S., but due to a difference in classification are generally not included in similar data published in many European countries. ***NMPF believes that U.S data which will include animal only antibiotics (such as ionophores) will be erroneously compared to European countries to disparage antibiotic stewardship of the U.S. dairy industry affecting competitiveness for the 15 percent of U.S. dairy production which is exported.***

Conclusions

The U.S. dairy industry is committed to the judicious and responsible use of antimicrobials and supports both transparency and good data on use and resistance for both animal and human use. FDA and its federal partners should present a comprehensive plan for antibiotic use data collection complete with justifications and goals rather than incomplete, ad-hoc approaches that only confuse the issue such as using estimated sales and distribution data divided by estimated biomass by species.

We believe that working with USDA to gather on-farm use data under the NAHMS program combined with defined goals is vital. Additionally, human use and resistance data needs to be effectively gathered and analyzed to understand the entire antimicrobial resistance picture to assure One Health solutions.

Please contact me if you have any questions about these comments.

Sincerely,

Jamie Jonker
Vice President, Sustainability & Scientific Affairs