



# National Milk Producers Federation

2107 Wilson Blvd., Suite 600, Arlington, VA 22201 | (703) 243-6111 | www.nmpf.org

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Agri-Mark, Inc.  
Associated Milk Producers Inc.  
Bongards' Creameries  
California Dairies Inc.  
Cooperative Milk Producers Association  
Dairy Farmers of America, Inc.  
Ellsworth Cooperative Creamery  
FarmFirst Dairy Cooperative  
First District Assoc.  
Foremost Farms USA  
Land O'Lakes, Inc.  
Lone Star Milk Producers  
Maryland & Virginia Milk Producers Cooperative Association  
Michigan Milk Producers Association  
Mid-West Dairyman's Company  
Mount Joy Farmers Cooperative Association  
Northwest Dairy Assoc.  
Oneida-Madison Milk Producers Cooperative Association  
Prairie Farms Dairy, Inc.  
Premier Milk Inc.  
Scioto Cooperative Milk Producers' Association  
Select Milk Producers, Inc.  
Southeast Milk, Inc.  
St. Albans Cooperative Creamery, Inc.  
Tillamook County Creamery Association  
United Dairymen of Arizona  
Upstate Niagara Cooperative, Inc.

December 24, 2019

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

**Re: Draft Guidance for Industry #263, Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue To be Available Over the Counter (Docket No. FDA-2019-D-3614)**

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.

NMPF is pleased with the Federal Register notice seeking comment on the Food and Drug Administration (FDA) draft Guidance for Industry (GFI) #263 entitled "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter." Among the measures available to treat and prevent the outbreak and spread of animal diseases among the nation's dairy cattle, the prudent 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.

NMPF has supported FDA's previous efforts to increase veterinary oversight in the use of medically important antimicrobials. In 2016, in response to recommendations made by FDA as part of a strategy to address AMR associated with the use of antimicrobial drugs in animal agriculture (as outlined in as outlined in GFI #209 and #213), pharmaceutical manufacturers of all medically important antimicrobial drugs approved for use in or on the feed or drinking water of food-producing animals worked with FDA to voluntarily withdraw approval of indications that were not considered necessary for assuring animal health (production indications), and voluntarily change all remaining approved uses of such new animal drugs from OTC to either Veterinary Feed Directive or Rx marketing status, as applicable.

In GFI #263, FDA proposes that pharmaceutical manufacturers voluntarily change the marketing status of medically important antibiotics for use in animals from Over-The-Counter (OTC) to prescription (Rx). This will increase veterinary oversight in the use of

medically important antimicrobials in animals in order to mitigate antimicrobial resistance (AMR).

***NMPF supports a process to transition the few remaining medically important antibiotics approved for use in dairy animals from OTC to Rx.***

### **Veterinary Oversight**

In GFI #263, FDA states “the judicious use of medically important antimicrobial drugs intended for use in animals should involve the scientific and clinical training of a licensed veterinarian.” A cornerstone of the National Dairy FARM Program: Farmers Assuring Responsible Management™<sup>1</sup>, the U.S. dairy industry on-farm social responsibility program, has been a Veterinarian-Client-Patient-Relationship (VCPR). The current VCPR standard<sup>2</sup> is to have a signed form annually with the veterinarian of record and the dairy farm owner or manager. The U.S. dairy industry is striving for all dairy farms to have a current VCPR, but we recognize that there are geographic and farm size differences in access to large animal veterinarians.

NMPF has analyzed data from 30,935 National Dairy FARM Program animal care evaluations conducted between January 1, 2017 and December 15, 2019 and found that 78% of dairy farms had a VCPR signed within the previous 12 months and 22% did not. This varied across regions and across farm sizes. For example, 89% of dairy farms in the Mountain Plains region had a VCPR signed within the previous 12 months while only 72% in the Northeast region did (Table 1). Smaller dairy farms were less likely to have a VCPR signed within the previous 12 months: 87% of dairy farms with more than 500 cows (Table 4) had a VCPR signed within the previous 12 months while only 75% of dairy farms with 100 cows or less did (Table 2). These regional and size differences are presented in Appendix 1.

***NMPF believes FDA must work with dairy farmers, veterinarians, and pharmaceutical manufacturers to assure the transition of the remaining medically important antimicrobials from OTC to Rx does not compromise animal health or food safety.***

### **Conclusions**

Antimicrobial stewardship goes beyond an individual dairy farmer’s action. It extends across all livestock production and use of antimicrobials in companion animals and humans. Misuse and overuse of antimicrobials is one of the world’s most pressing public health concerns. Infectious organisms adapt to antimicrobials designed to kill them, making the drugs less effective. NMPF supports a process to transition the few

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<sup>1</sup> <https://nationaldairyfarm.com/> accessed December 24, 2019

<sup>2</sup> <https://nationaldairyfarm.com/wp-content/uploads/2018/11/Veterinary-Client-Patient-Relationship-Form.pdf> accessed December 24, 2019

remaining medically important antibiotics approved for use in dairy animals from OTC to Rx.

The U.S. dairy industry is committed to producing the highest quality, safe, abundant and affordable milk and dairy beef. Healthy animals help make for safe food, and disease prevention is the key to keeping cows healthy. When dairy animals get sick and treatment is necessary, producers and veterinarians utilize antibiotics and other drugs prudently. NMPF stands ready to work with FDA, dairy farmers, veterinarians, and pharmaceutical manufacturers to assure the transition of the remaining medically important antimicrobials from OTC to Rx does not compromise animal health or food safety.

Thank you for the opportunity to comment on this important matter.

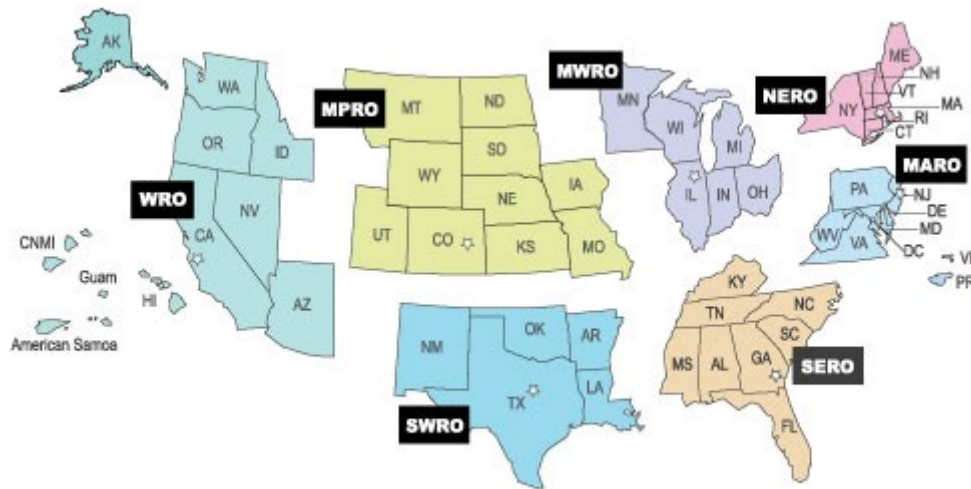
Sincerely,

A handwritten signature in purple ink that reads "Jamie Jonker". The signature is written in a cursive style with a large, stylized initial "J".

Jamie Jonker, Ph.D.  
Vice President  
Sustainability & Scientific Affairs

## Appendix 1

**Figure 1. Regions of the United States used in analysis of dairy farms with a Veterinarian-Client-Patient-Relationship signed within the previous 12 months.**



**Table 1. Percentage of dairy farms by region with a Veterinarian-Client-Patient-Relationship signed within the previous 12 months.**

Region	Total with VCPR	Total Evaluations	Share with VCPR
Western	1,749	2,026	86%
Mountain Plains	2,318	2,619	89%
Southwest	646	790	82%
Midwest	10,889	13,977	78%
Northeast	3,258	4,550	72%
Midatlantic	4,172	5,665	74%
Southeast	990	1,308	76%
<b>Nationwide</b>	<b>24,022</b>	<b>30,935</b>	<b>78%</b>

**Table 2. Percentage of dairy farms by region with 100 cows or less with a Veterinarian-Client-Patient-Relationship signed within the previous 12 months.**

Region	Total with VCPR	Total Evaluations	Share with VCPR
Western	135	161	84%
Mountain			
Plains	1,340	1,553	86%
Southwest	152	181	84%
Midwest	7,296	9,548	76%
Northeast	2,303	3,264	71%
Midatlantic	3,271	4,515	72%
Southeast	538	752	72%
<b>Nationwide</b>	<b>15,035</b>	<b>19,974</b>	<b>75%</b>

**Table 3. Percentage of dairy farms by region with 101 to 500 cows with a Veterinarian-Client-Patient-Relationship signed within the previous 12 months.**

Region	Total with VCPR	Total Evaluations	Share with VCPR
Western	407	492	83%
Mountain			
Plains	672	747	90%
Southwest	173	198	87%
Midwest	2,744	3,473	79%
Northeast	645	907	71%
Midatlantic	799	1,032	77%
Southeast	325	413	79%
<b>Nationwide</b>	<b>5,765</b>	<b>7,262</b>	<b>79%</b>

**Table 4. Percentage of dairy farms by region with more than 500 cows with a Veterinarian-Client-Patient-Relationship signed within the previous 12 months.**

Region	Total with VCPR	Total Evaluations	Share with VCPR
Western	1,207	1,373	88%
Mountain			
Plains	306	319	96%
Southwest	321	411	78%
Midwest	849	956	89%
Northeast	310	379	82%
Midatlantic	102	118	86%
Southeast	127	143	89%
<b>Nationwide</b>	<b>3,222</b>	<b>3,699</b>	<b>87%</b>

