March 13, 2017

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

RE: [Docket No. FDA-2016-D-2635] Establishing Appropriate Durations of Therapeutic Administration

Dear Sir or Madam:

The AVMA welcomes the opportunity to provide comments regarding the establishment of appropriately targeted durations of use of antimicrobial drugs of importance to human medicine when they are administered in the feed or water of food-producing animals for therapeutic purposes. The AVMA recognizes this activity is consistent with previous FDA efforts to protect public health and supports the science-based processes of the FDA in the regulation of antimicrobials for their intended use in food animals.

The AVMA recognizes that the availability of antimicrobials for use in food-producing animals is essential to maintain the safety of the US food supply and believes that veterinarians should be at the forefront of discussions that may impact drug availability, such as regulatory changes in veterinary oversight.

In regards to the FDA’s specific questions relative to species-specific disease indications with approved therapeutic indications with undefined durations of use, please see the attached addendum. The AVMA recognizes that many of our allied species-specific veterinary groups will also be submitting comments.

The AVMA, founded in 1863, is one of the oldest and largest veterinary medical organizations in the world, with more than 89,000 member veterinarians worldwide engaged in a wide variety of professional activities and dedicated to the art and science of veterinary medicine. We thank the FDA for the opportunity to provide our input. For questions regarding the AVMA’s comments, please contact Dr. Michael Costin at 847-285-6634 or mcostin@avma.org.

Sincerely,

Janet D. Donlin, DVM, CAE
Executive Vice President and CEO

Attachment 1: Indications and therapeutic durations tables for chickens, turkeys, and sheep