June 26, 2012

The Honorable Margaret Hamburg, MD  
Commissioner, Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: Comment on Draft Guidance for Industry #213  
Docket No. FDA-2011-D-0889

Dear Commissioner Hamburg:

The Alliance for the Prudent Use of Antibiotics appreciates the opportunity to comment on this Draft Guidance for Industry #213 intended to implement FDA’s Final Guidance 209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” We applaud the FDA’s Final Guidance #209 which focuses on two tenets intended to promote judicious use of antimicrobials in food animal production: 1) withdrawal of the use of important antimicrobials in food animals for promotion of growth and/or feed efficiency and 2) veterinary oversight in the dispensing of antimicrobials—particularly in feed and water, where whole herds and flocks are the recipients.

These new FDA provisions represent a significant shift in U.S. public health protection and begin to address the high risks that non-judicious use of antimicrobials in food animals pose for human health. While these provisions put industry on notice, they are insufficient to reduce drug resistance and avoid potential treatment failures.

We recommend specific refinements in FDA guidance to ensure they attain their objectives:

- **The guidance is voluntary.**  
  *Recommendation:* Require industry to comply with the recommendations for product labeling; Require veterinary oversight/obligatory prescriptions for all antimicrobials used for disease control in food animals.¹ ²  

- **FDA considers “treatment, control, and prevention of specific diseases to be therapeutic uses” essential to animal health.**  
  *Recommendation:* Withdraw approval of use of antibiotics for prevention purposes; Define clearly prevention, control & treatment; Use antibiotics only to treat disease in target animals. Use alternative strategies, if possible, for disease prevention and control: vaccines, use of probiotics, improved animal hygiene, husbandry and management practices. Consider workable strategies to mitigate “stress” factors which place animals at risk for disease.

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¹ WHO Recommendations, 2001, WHO Global Strategy for Containment of Antimicrobial Resistance, Use of Antimicrobials in Food Producing Animals, p. 5  
² FAAIR Report, Clinical Infectious Diseases, The Need to Improve Antimicrobial Use in Agriculture, 2002:34 (Suppl 3)
Draft Guidance #213 uses a truncated method to assess safety of new animal drugs to be used in food animal production, based on the methodology described in Industry Guidance #152.  

Recommendation: Strengthen Draft Guidance #213 to be on a par with qualitative risk assessment process model adapted from OIE and described in Guidance #152 to include all relevant factors in the release assessment (occurrence and rate of transfer of resistance determinants, resistance selection pressures, baseline prevalence of resistance); include recommendations on the use of medically important antimicrobials in herds and flocks, with specific dosages and duration; take additional risk managements steps, such as “post-approval monitoring” through NARMS.

FDA alludes to challenges of implementing the veterinary oversight system for small producers in remote geographical areas, where there is a shortage of veterinarians.  

Recommendation: Educate animal husbandry workers on disease prevention, and judicious use of antibiotics via agricultural extension programs, and rotation service of public health veterinarians. Ensure that veterinarians have access to appropriate prescribing literature on individual drugs. Provide incentives for veterinary professional organizations and schools to provide training.

Methods of monitoring progress are not clearly described, save the adoption of changes will be evaluated in three years time. Surveillance and data collection are foundations of any public health program, providing the wherewithal to evaluate the outcome of proposed changes and guide future efforts.  

Recommendation: Create a national integrated surveillance system to monitor antimicrobial resistance and usage in both animals and humans. Integrated mandatory reporting is necessary to monitor practitioner compliance and antimicrobial use in specific animal species and herds/flocks.

Withdrawal of growth promoters is an important step in reducing antibiotic overuse and minimizing the public health threat of untreatable human infections, and for this we applaud FDA. Other interventions, however, must be adopted in tandem – including appropriate monitoring and infection prevention and control measures, if an overall reduction in antimicrobial use is to be achieved. APUA stands ready to work with FDA to facilitate a path which will result in greater protection of public health, building on the groundwork laid at its recently convened National Stakeholder Meeting on “Improving Antimicrobial Use in Food Animal Production: Alternative, Options, and Incentives”.

Sincerely,

[Signature]

Kathleen Young  
Executive Director

[Signature]

Carol Coglian, EdM, MPH  
Program Manager

About APUA  
The Alliance for the Prudent Use of Antibiotics (APUA) www.apua.org, has been the leading global non-governmental organization fighting to preserve the effectiveness of antimicrobial drugs since 1981. With affiliated chapters in over 65 countries, we conduct research, education and advocacy programs to control antimicrobial resistance and ensure access to effective antibiotics for current and future generations.