

Protein Sources Swine Update March/April 2013 Lori Feldmann, DVM

The Animal Drug User Fee Act (ADUFA) is likely something many of you have never heard of and you may be wondering why we would choose to dedicate a Swine Update to this topic. ADUFA was first passed by Congress in 2003 and was reauthorized in 2008. It expires in September 2013 and now needs to be reauthorized by Congress, so it has been a recent topic of discussion in the Senate Health Education Labor and Pensions (HELP) committee.

ADUFA is an amendment to the Federal Food, Drug, and Cosmetic Act and allows the Food and Drug Administration (FDA) to collect fees for certain animal drug applications to support review of these applications. This expedites and improves FDA review of these applications so safe and effective new products can be made available more quickly. From this, the government receives over \$25 million in user fees, animal drug companies are able to get their products on the market more quickly, and pork producers can then start using new products more quickly. It seems like this should be a winning situation for all parties involved, unless of course you are opposed to animal agriculture.

When ADUFA was reauthorized in 2008 there was an amendment added to require reporting of antibiotic sales in each calendar year. Now the same groups that pushed for the 2008 amendment are requesting the additional reporting as an attempt to build their case against antibiotic use in animal agriculture. For the 2013 reauthorization, Senators Gillibrand (D-NY) and Feinstein (D-CA) strongly encouraged the HELP committee to include language that would require this extra reporting on antibiotic use. One of the issues with increased reporting is that many antibiotics used in animal agriculture are approved for multiple species and at more than one dosage. The only means of reporting some of this specific information would be to collect additional data from vet clinics, feed mills, and farms.

The FDA has already published guidance and proposed rules in the past year that will change how we use antibiotics in animal agriculture. One other item published by the FDA is an Advanced Notice of Proposed Rulemaking on data collection of antibiotic use in animals, which the FDA is currently considering comments on. The FDA's mission is to protect public health, so it makes sense that they should be allowed to determine what is necessary reporting for antibiotic use rather than legislating it as part of ADUFA.

ADUFA has made it through the HELP committee without any of the data collection amendments, but still has some challenges ahead. Senators Gillibrand and Feinstein are objecting to it being passed by unanimous consent, so the committee is looking for solutions to allow it to move. The House Energy and Commerce Committee will be looking at the bill on April 9 and Representative Waxman (D-CA) is expected to push for the data collection amendments to be added to this version.

Through this whole process, the National Pork Producers council has been a strong voice for reauthorization of ADUFA without the reporting amendments. Dr. Liz Wagstrom with the NPPC said, "NPPC is hopeful that by working on this issue with the other commodity and animal health groups that it will get through the process and be reauthorized without any additional data reporting requirements that would be onerous to pork producers and unlikely to provide any useful information on the epidemiology of antibiotic resistance."

ADUFA and other agriculture regulations are examples of why it is important to communicate with your legislators and promote agriculture issues.