What's New in Washington, D.C.

Richard Sellers, Sr. Vice President, Legislative and Regulatory Affairs
American Feed Industry Association
Arlington, Virginia

Food Safety Modernization Act

The Food Safety Modernization Act was signed into law in January 2011. Proposed rules for animal food have been published twice, and final rules must be published by August 2015 to comply with a federal court order. The rules are substantial and cover current good manufacturing practices (CGMPs), hazard analysis, preventive controls, supplier verification, environment/product testing and recordkeeping, among many other items.

The rules require compliance by each facility that manufacturers process pack or hold food, feed, ingredients or pet food, unless the facility is a farm. "Farm" for livestock purposes are those that feed animals on the their own land. These facilities need not register and are therefore exempt from the requirements of FSMA.

Feed industry organizations have reviewed the rules in-depth and noted to the Food and Drug Administration (FDA) that compliance with the rules would be very expensive (>$600 million), the rules are more geared toward the food industry, are overly prescriptive and are not practical for the U.S. animal food industry, which includes feed and pet food.

Comments by the American Feed Industry Association (AFIA) note that most significant hazards in feed mills can be controlled by CGMPs, thereby not requiring preventive controls. Such an approach could significantly reduce the total costs of the rules. Also, AFIA said the timelines for compliance are not long enough, and AFIA will provide data indicating that more time is needed by the industry to comply.

FDA has established the Food Safety Preventive Controls Alliance, which set up the Animal food Safety Preventive Controls Alliance to develop a framework for training and to develop guidance and example documents. This group is currently operating by developing the documents and structure necessary to do training and assist with compliance of the new rules by FDA-registered facilities.

For more information on FSMA, visit FDA's website here: www.fda.gov/fsma.

Veterinary Feed Directive (VFD)

The VFD process was codified in 1996 by Congress in the Animal Drug Availability Act. Within a year the first VFD animal drug was approved. Since that time, the same product has been approved for beef, as well, and another compound has been approved for use in pigs, catfish and salmonids. The use of these compounds governed by the applicable federal animal drug regulations and the VFD rules. Such use requires the authorization by a licensed veterinarian via the VFD process.

In 2013, FDA proposed that all growth promotion, feed efficiency and milk production claims should be voluntarily removed and therapeutic claims with veterinarian oversight should be utilized. This would encompass 29 drug sponsors, all of which have agreed to this change, with about 15 chemical entities involving 283 claims—a monumental undertaking by the feed industry and FDA. These changes must be effected by drug sponsors before December 2016, according to FDA.

Along with the changes, FDA decided, at the feed industry's request, to update the VFD rules that govern how the process works. Of particular concern were the administrative burdens placed on the feed industry by an outdated VFD form and system. FDA has provided two draft VFD rule changes and is expected to publish a final rule in April 2015 adopting all of the feed industry's requested change.

Discussions with the animal drug and feed industries have taken place on several occasions. There are efforts to create a model VFD form, a timeline for the changes, method for roll-out of the changes and other relevant topics. Of particular concern is what to do about existing product in the marketplace when the changes are made to each animal drug. What FDA will allow in implementation time of any new rule and new products is the main issue.

FDA and the animal drug and feed industries will provide education campaigns on the newly updated VFD rule after it publishes. The feed industry anticipates doing webinars, guidance documents and meetings to assist with compliance of the new procedures. It will also survey its members close to the time of the drug sponsor changes to determine who much existing Type A medicated articles (drug premixes) are in the marketplace. This will assist in determining whether the industry will request additional implementation time to exhaust supplies of old product and phase-in the new product. For more information on VFD, visit FDA's website here: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm.