

November 16, 2012

The Honorable Margaret Hamburg, M.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

The Honorable Mike Taylor, Esq.  
Deputy Commissioner for Food  
U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

**RE: FDA action need to remedy FDAAA for language interpretation for animal food ingredients**

Dear Commissioner Hamburg and Deputy Commissioner Taylor:

The national organizations signed below represent U.S. livestock and poultry production, and we write to urge your immediate executive action to address a technical language anomaly contained in the Food & Drug Administration Amendments Act of 2007 (FDAAA) threatening not only the future efficiency of the federal animal feed ingredient approval process, but the productive 30-plus-year relationship between FDA and state feed ingredient officials on the approval of ingredients for use in animals other than man.

For more than 30 years, FDA and the Association of American Feed Control Officials (AAFCO) have cooperated successfully in the AAFCO ingredient definition approval process. FDA meets its federal safety/efficacy review responsibilities for prospective ingredients, aided by technical reviews of animal food ingredients accepted by AAFCO and subsequently listed in the AAFCO *Official Publication* (OP). At the same time, AAFCO members are able to meet specific requirements of the model state feed law adopted by most states.

In 2007, pet food ingredient language was added to FDAAA in the wake of the imported Chinese melamine situation directing FDA to develop “ingredient standards” for pet foods. Significantly, Senate authors of the FDAAA pet food language recognized the importance of FDA’s cooperative agreement with AAFCO – the AAFCO president testified during hearings on melamine contamination in imported pet food ingredients – and the FDAAA requirements were not intended to undermine or interfere with the FDA/AAFCO ingredient-approval process.

The Center for Veterinary Medicine (CVM) subsequently announced it would develop such “standards” for all animal foods, given livestock/poultry feeds and pet foods are regulated in the same manner. The word “standard” was intended to be synonymous with “definition;” however, the absence of the word “standard” in relevant sections of the Federal Food, Drug & Cosmetic Act (FFDCA) is causing confusion within the agency. If this confusion is not addressed in a realistic, logical and timely manner, it could result in the elimination of the current FDA/AAFCO cooperative ingredient approval process.

Our concern centers on FDA’s apparent unwillingness to internally remedy the problem, and with a precious few days left in the 112<sup>th</sup> Congress, a legislative fix may be impossible. If left unaddressed, this language issue threatens the federal feed ingredient authorization process, the

status of already-approved ingredients and state feed ingredient regulation/approvals. Such a development would negatively impact our farmer/rancher members at a time when yet another cost-of-production challenge can be ill-afforded.

We strongly support efforts by the American Feed Industry Association (AFIA), the National Grain & Feed Association (NGFA) and the Pet Food Institute (PFI) urging FDA to accept apparent congressional intent in equating the term “standard” with “definition.” We strongly urge FDA to apply its discretion to this situation and accept these two words as synonymous. Doing so would represent a common-sense, fiscally responsible and efficient solution to this issue, and immediately remove the threat to the existing federal feed ingredient- approval process and the FDA/AAFCO cooperative arrangement.

Your support, understanding and work to secure this timely remedy is greatly appreciated.

Sincerely,

American Farm Bureau Federation  
American Sheep Industry Association  
National Cattlemen’s Beef Association  
National Chicken Council  
National Milk Producers Federation  
National Pork Producers Council  
National Turkey Federation  
United Egg Producers

cc: Dr. Bernadette Dunham, CVM Director  
Sen. Tom Harkin, chair, Senate Health, Education, Labor & Pensions Committee  
Sen. Mike Enzi, ranking, Senate Health, Education, Labor & Pensions Committee  
Sen. Richard Durbin  
Rep. Fred Upton, chair, House Committee on Energy & Commerce  
Rep. Henry Waxman, ranking, House Committee on Energy & Commerce