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 needed to remedy FDAAA language interpretation for animal food ingredients**

Dear Commissioner Hamburg and Deputy Commissioner Taylor:

The state grain, feed and agribusiness organizations signed below represent thousands of feed ingredient companies and feed manufacturers, including pet food companies. We're writing to urge you to take immediate executive action to address a technical language anomaly contained in the Food & Drug Administration Amendments Act of 2007 (FDAAA). This rigid FDA language interpretation threatens the efficiency of the federal animal feed ingredient approval process, as well as the productive 30-plus-year relationship between FDA and state feed ingredient officials on the approval of feed ingredients for use in animals.

In 2007, pet food ingredient language was added to FDAAA following the imported Chinese melamine contamination issue, language instructing 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 the Association of American Feed Control Officials (AAFCO), demonstrated by the president of the state feed control officials' organization testifying at the Senate hearing on melamine contamination in imported pet food ingredients. It's clear the FDAAA requirements were not intended to undermine or interfere with the FDA/AAFCO ingredient-approval process, particularly since these definitions are referenced in all state feed laws as the list of legal ingredients for use in commercial feed and pet food.

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 by Congress to be synonymous with "definition;" however, because "standard" isn't used in animal feed sections of the Federal Food, Drug & Cosmetic Act (FFDCA), a rigid FDA legal interpretation has evidently has delayed action by the agency. If this confusion isn't addressed in a common sense and timely way, it may mean the end of the current FDA/AAFCO cooperative ingredient-approval process.

We urge FDA to solve this problem administratively. An administrative solution would be the common-sense, fiscally responsible solution to this issue, and one that

immediately would remove the threat to the existing federal feed ingredient-approval process and the FDA/AAFCO cooperative arrangement. Without administrative action, the only option is to ask Congress to intervene. However, with precious few days left in the 112th Congress, a legislative fix may be impossible.

That is why 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 the apparent congressional intent equating the term "standard" with "definition." For more than 30 years, FDA and AAFCO have cooperated successfully in the AAFCO ingredient definition-approval process, with FDA meeting its federal safety/efficacy review responsibilities for prospective ingredients utilizing technical reviews of animal food ingredients accepted by AAFCO and subsequently listed in the AAFCO Official Publication (OP). At the same time, AAFCO state members are able to meet specific requirements of the model state feed law adopted by most states.

The long-term relationship between state feed control officials and FDA produces many benefits, especially the strong working relationship relative to the animal food ingredient-approval process. We know AAFCO is seriously concerned the relationship with FDA will be strained if this issue is not resolved, which would lead to the end of the highly productive joint review of the safety and utility of feed ingredients.

The end of this joint review relationship is scheduled for September 1, 2013, because the FDA/AAFCO joint Memorandum of Understanding (MOU) expires on that date. The MOU facilitates FDA's collaboration with AAFCO in the AAFCO New and Modified Feed Ingredient Definition Process, clarifying the responsibilities of FDA and AAFCO in the definition review. Further, we've been informed by FDA/CVM that the de facto end of the ingredient-application process will come even earlier, as the agency plans in January, 2013, to announce when companies will no longer be able to submit AAFCO-reviewed ingredients for FDA approval.

In closing, we urge you to make an executive decision to remedy this problem administratively.

Thank you for your consideration of our views.

Sincerely,

Agribusiness Association of Iowa
Agribusiness Council of Indiana
California Grain & Feed Association
Grain & Feed Association of Illinois
Kansas Grain & Feed Association
Michigan Agri-Business Association
Minnesota Grain & Feed Association
Montana Feed Association

Nebraska Grain & Feed Association
North Dakota Grain & Feed Association
Northeast Ag & Feed Alliance
Ohio Agribusiness Association
Oklahoma Grain & Feed Association
Rocky Mountain Agribusiness Association
South Dakota Grain & Feed Association
Texas Grain & Feed Association
Wisconsin Agri-Business Association

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