January 30, 2008

The Honorable Michael Leavitt
Secretary of Health & Human Services
U.S. Department of Health & Human Services
Room 615F
Hubert H. Humphrey Building
200 Independence Avenue Southwest
Washington, DC 20201

The Honorable Ed Shafer
Secretary of Agriculture
U.S. Department of Agriculture
Room 200A
Jamie L. Whitten Federal Building
1400 Independence Avenue Southwest
Washington, DC 20250

The Honorable James Nussle
Director
Office of Management & Budget
Eisenhower Executive Office Building
1650 Pennsylvania Avenue Northwest
Washington, DC 20503

The Honorable Susan Schwab
Ambassador, Special Trade Representative
Office of U.S. Trade Representative
Room 209A
Winder Building
600 17th Street Northwest
Washington, DC 20506

Dear Secretary Leavitt, Secretary Shafer, Ambassador Schwab and Director Nussle:

The groups signed below represent America's livestock and meat industry, and we write to inform you of our collective opposition to publication at this time of the Food & Drug Administration's (FDA) proposed final rule on restricted use protein product feeding ("the feed rule") to mitigate the risk of bovine spongiform encephalopathy (BSE) in the U.S. The central reason for our opposition is straightforward: The pending final rule is unnecessary, will do little to further reduce already very low U.S. BSE risk, will impose unreasonably high compliance costs and may lead to significant industry dislocation.

Our opposition is predicated upon the near-nonexistent BSE risk in the U.S. in the wake of highly successful government and industry actions over the last 20 years. The following lists why publication of an FDA final rule is unnecessary and/or unwise at this time:

- The risk of BSE in the U.S. is miniscule, certainly much lower today than when the FDA proposed final rule was published in 2005. Each year the probability of BSE in the U.S. drops because an effective, precautionary mammalian-to-ruminant feed ban was implemented in 1997. In addition to the FDA feed rule, industry segments have voluntarily implemented and maintained their own BSE "fire walls," including self-inspection and third party certification programs, affidavits and other measures. The U.S. Department of Agriculture (USDA) tested nearly 800,000 high-risk cattle at rendering and slaughter facilities and concludes the risk of BSE is negligible.

- The industry compliance rate with the FDA feed rule is consistently near 100% based on FDA reports of inspections and enforcement actions. The USDA-contracted Harvard/Tuskegee study confirms full compliance with the feed rule is the most effective way to protect against the spread of BSE. The contemplated removal of brains and spinal cords from rendering, and as an ingredient in all animal feeds, is a costly and redundant action since the existing rule prevents these materials from being fed to ruminants.

- FDA continues to dramatically underestimate the economic impact of its proposed rule. FDA has publicly acknowledged its recalculation of the rule's cost based upon economic data submitted in 2005 by the National Renderers Association (NRA). This outside economic analysis shows the likely cost in 2005 to be nearly $128 million, a cost that will greatly exceed any measurable disease mitigation or other benefit, and which has no doubt grown over the two years the rule has pended.

- The proposed rule contemplates removal of the brain and spinal cord from animals 30 months or older if inspected and passed for human consumption; the brain and spinal cord from animals of any age not inspected/passed for human consumption, and the entire carcass of cattle not inspected/passed if these specified risk materials (SRM) have not been removed. To remove the brain and spinal cord at slaughter will be very difficult and costly, effectively requiring removal of the head and the vertebral column and resulting in the disposal of more than 400 million pounds of product from slaughter plants alone.

- The proposed rule would create near-impossible requirements for independent renderers to meet if they continue to pick up cattle which die on the farm. The rule would devalue or make impossible to salvage material from fallen stock, likely leading to cessation of on-farm pickup of not only cattle but other species as well since the cost of running trucks for pick up could not be recouped. For those companies which may continue on-farm pickup, the average $25 fee renderers charge today for pick up is estimated to rise to $85-100. Some producers cannot afford such an increase and this will lead to on-farm disposal challenges.

- The impact of potentially restricted rendering services affects not only farmers, ranchers and feed companies, but also livestock marketing. With consolidation in the rendering industry, it's already difficult for some livestock auction markets to get pickup of fallen stock. Even without further restriction of rendering services, disposal alternatives are limited either because they are prohibitively expensive or environmentally unacceptable.

- While we obviously do not know how FDA may have changed its approach to SRM definitions or age distinctions in its final rule, it's difficult to imagine any "short list" of SRM or an animal age cut off which would make SRM removal from dead stock practical, enforceable or safe for plant workers.

- Given we've received no concrete direction from FDA to date on the appropriate and legal disposal of the increased amounts of SRM, carcasses, etc. that will result from implementation of the proposed final rule – despite repeated discussions with and requests of FDA, USDA and the Office of Management & Budget (OMB) during the two years the proposal has pended – we have little confidence a final rule will provide any greater guidance in this critical area.

In summary, we strongly urge FDA to withhold publication of its final feed rule at this time. The contemplated rule is not justified based on the *possible* mitigation of a miniscule risk of BSE in the U.S. We urge the Administration to remain focused on the food safety, animal and human health goals of FDA's current successful BSE mitigation efforts, and to ignore political and unrelated pressures to move this unnecessary and costly rulemaking forward.

Thank you for consideration of our views. Please feel to contact any of the organizations listed below if you need further information.

Sincerely,

American Association of Meat Processors
American Feed Industry Association
American Meat Institute
American Sheep Industry Association
American Veal Association
Livestock Marketing Association
North American Meat Processors Association
National Cattlemen's Beef Association
National Meat Association
National Milk Producers Federation
National Pork Producers Council
National Renderers Association

cc: The Honorable Charles Conner, deputy secretary, USDA
Dr. Andrew von Eschenbach, commissioner, FDA
Dr. Bernadette Dunham, director, Center for Veterinary Medicine, FDA
Dr. Stephen Sundlof, director, Center for Food Safety & Applied Nutrition, FDA
Susan Dudley, director, Office of Information & Regulatory Affairs, OMB
The Honorable Bruce Knight, undersecretary for marketing & regulatory programs, USDA
Barry Jackson, assistant to the President, the White House
Hunter Moorhead, special assistant to the President, the White House
The Honorable Richard T. Crowder, USTR