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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: R-CALF USA Comments in Docket Number: FDA-2002-N-0031 (formerly Docket No. 2002N-0273), RIN 0910-AF46.

Dear Administrator,

R-CALF USA (Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America) is a national, nonprofit organization dedicated to ensuring the continued profitability and viability of the U.S. cattle industry. R-CALF USA represents thousands of U.S. cattle producers on trade and marketing issues. Our members are located across the U.S. and are primarily cow/calf operators, cattle backgrounders, and/or feedlot owners, and there are numerous affiliated organizations and various main-street businesses that are associate members. R-CALF USA appreciates this opportunity to comment on Docket No. FDA-2002-N-0031 (formerly Docket No. 2002N-0273), RIN 0910-AF46, found at 74 Fed. Reg., 16160, 162.

I. INTRODUCTION

R-CALF USA members have fought against the previous Administration's efforts to irresponsibly expose U.S. consumers and the U.S. cattle herd to the increased risk of bovine spongiform encephalopathy (BSE) from Canada and other foreign countries for as long as the U.S. Food and Drug Administration (FDA) has been trying to enhance the U.S. ruminant-to-ruminant feed ban.¹ The most aggressive adversaries against our efforts have been the National Cattlemen's Beef Association (NCBA) and the American Farm Bureau Federation (AFBF).

The NCBA and the AFBF filed a brief on April 21, 2005, in opposition to the second of three court-ordered preliminary injunctions won by R-CALF USA that enjoined the U.S. Department of Agriculture (USDA) from prematurely relaxing U.S. border protections that safeguarded the U.S. against the introduction of BSE. In their opposing brief, these two industry associations asserted that "Canada's feed ban [the original feed ban implemented in 1997] of nearly 8 years *is more than sufficient* to mitigate the risk of BSE spreading to the United States." (Emphasis added.) Fortunately, and as discussed more fully below, science ultimately prevailed and the fallacy of this irresponsible claim was revealed. Soon after this baseless claim was made,

¹ See Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission, United States Department of Health and Human Services, News Release, January 26, 2004.

Canada announced it would upgrade its feed ban because its feed ban continued to allow the amplification and spread of BSE in Canadian cattle. These two trade associations also have instigated this *last-minute* initiative to undermine FDA's attempts to timely implement the science-based risk mitigation measure, i.e., the enhanced feed ban, that is sorely needed to address the United States' ongoing exposure to a heightened risk of BSE introduction and spread.²

R-CALF USA recommends that the first thing FDA must do regarding this instant docket is quit listening to these corporate-controlled, self-serving trade associations that have greatly contributed to the significantly increased food safety risks now faced by U.S. citizens.

II. PROTECTING THE HEALTH AND SAFETY OF U.S. CONSUMERS AND U.S. CATTLE HERD

Under no circumstances should the U.S. Food and Drug Administration (FDA) delay its April 27, 2009, scheduled implementation of the final rule entitled, "Substances Prohibited from Use in Animal Food or Feed," commonly referred to as the 2008 BSE final rule, particularly while the U.S. Department of Agriculture (USDA) continues to subject U.S. consumers and the U.S. cattle herd to a heightened risk of bovine spongiform encephalopathy (BSE) from Canadian live cattle imports, particularly imports of Canadian cattle over 30 months (OTM) of the age.

Protections for U.S. consumers and the U.S. cattle herd against the ongoing and increased BSE exposure caused by USDA's relaxed import restrictions should not be held hostage by the very trade associations who fought to accept Canada's higher-risk cattle without first supporting and implementing even the science-based feed-ban upgrades the Canadian experience has proved necessary to attempt to mitigate the higher BSE-risk associated with Canadian cattle. Just in 2008, nearly 1.6 million Canadian cattle were imported into the United States.³

Scientific studies have linked BSE to cases of variant Creutzfeldt-Jakob Disease (vCJD) in humans, an invariably fatal disease that most likely results from human consumption of infectious material from cattle with BSE. As of February 2009, there have been 212 human deaths caused by vCJD in 11 countries, including the United Kingdom, and there are five known living humans with the disease.⁴

A. The U.S. is Exposed To An Unacceptable Risk of BSE from Canadian Imports

U.S. consumers and the U.S. cattle herd are now subjected to a heightened risk from BSE because the U.S. continues to import millions of live cattle from Canada, where the disease prevalence is believed to be between three cases per million to eight cases per million cattle. The U.S. Centers for Disease Control and Prevention (CDC) states this level of BSE prevalence in

² See e-Dear Colleague Letter from the Honorable Adrian Smith, U.S. House of Representative, March 17, 2009.

³ See Livestock and Meat Trade Data, Cattle: Annual and Cumulative Year-to-Date U.S. Trade (Head), U.S. Department of Agriculture Economic Research Service, available at <http://www.ers.usda.gov/data/meattrade/CattleYearly.htm>.

⁴ See Variant Creutzfeldt-Jakob Disease, Current Data (February 2009), The National Creutzfeldt-Jakob Disease Surveillance Unit, the University of Edinburgh, Scotland, available at <http://www.cjd.ed.ac.uk/vcjdworld.htm>.

the Canadian cattle herd is 18-fold to 48-fold higher than the prevalence estimated in the U.S. cattle herd.⁵

When USDA reopened the U.S. border in 2007 to Canada's highest-risk cattle population – OTM cattle, its base-case risk modeling predicted that 19 BSE-infected cattle would enter the U.S., resulting in the subsequent infection of two U.S. cattle over the next 20 years.⁶ Human exposure to BSE also was predicted to increase over 15 percent when compared to the earlier base-case modeling conducted in 2003 by Harvard University.⁷ When USDA modeled the risk of importing Canadian OTM cattle using the higher-than-base-case BSE prevalence estimate for Canada of 3.9 per million, which prevalence estimate USDA stated was “far more likely to be true,”⁸ the model predicted that the U.S. would import, at the 95th percentile confidence level, 105 BSE-infected cattle, resulting in the subsequent infection of 75 U.S. cattle.⁹ And, human exposure, also using this “far more likely to be true” prevalence estimate and also at the 95th percentile confidence level, increased over 1,870 percent when compared to the earlier base-case modeling conducted in 2003 by Harvard University.¹⁰ Importantly, the 3.9 per million prevalence estimate used in USDA's model is *far less* than the upper range of the CDC's prevalence estimate of 8 cases per million cattle, meaning that USDA likely has *grossly* underestimated the risk of introducing BSE-infected cattle into the U.S. as a result of allowing OTM Canadian cattle imports.

USDA's risk modeling, based again on the BSE prevalence level for Canada that USDA claims is “far more likely to be true,” reveals that the U.S. already has likely imported 5 head of BSE-infected cattle from Canada during the first year that OTM Canadian cattle were reintroduced into the U.S. – beginning November 19, 2008.¹¹ This number, however, was based on the expectation that fewer than 1.4 million Canadian cattle would be imported into the United States.¹² As mentioned above, the U.S. imported nearly 1.6 million cattle from Canada in 2008, meaning USDA likely underestimated the number of BSE-infected cattle that are expected to already have entered the United States, without even the minimal protection of an upgraded U.S. feed ban similar to Canada's new feed ban, which Canada *hopes* is capable of addressing the heightened BSE risk in Canadian cattle.

⁵ See BSE (Bovine Spongiform Encephalopathy, or Mad Cow Disease), U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, available at <http://www.cdc.gov/ncidod/dvrd/bse/index.htm>.

⁶ See 72 Federal Register, 1109, col. 2 (“Using a base-case assumption . . . over the next 20 years, our quantitative model predicts the importation of a total of approximately 19 infected bovines over that period under the provisions of this proposed rule.”).

⁷ See Appendix 2A, Base Case, Harvard Model of Bovine Spongiform Encephalopathy Implications of Importing Cattle Over 30 Months of Age from Canada, Joshua T. Cohen, Ph.D., Center for the Evaluation of Value and Risk, Institute for Clinical Research and Health Policy Studies, Tufts New England Medical Center, October 27, 2006; see also Appendix 3A – Tables, Section 1 – Base Case: Import of 10 Infected Animals, Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Joshua T. Cohen, et al., Harvard Center for Risk Analysis, Harvard School of Public Health, Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001, Revised October, 2003.

⁸ 72 Federal Register, at 53327, col. 2.

⁹ See 72 Federal Register, at 53347, col. 1.

¹⁰ See footnote 4 above.

¹¹ See Revised Assessment of Bovine Spongiform Encephalopathy (BSE) Risks Associated with the Importation of Certain Commodities from BSE Minimal Risk Regions (Canada), U.S. Department of Agriculture Animal and Plant Health Inspection Service, Veterinary Services, September 2007, at 61.

¹² See *id.*, at 57.

B. The Current U.S. Feed Ban is Inadequate to Address the Known BSE Risk

The current U.S. feed ban implemented in 1997 is comparable to the initial Canadian feed ban also implemented in 1997. Canada's feed ban proved ineffective at preventing the spread of BSE in Canada. The Canadian Food Inspection Agency (CFIA) found that the 1997 feed ban was insufficient to eradicate BSE and stated in regard to its July 2007 feed ban upgrade, "Based on risk analysis, BSE eradication, which is estimated to have taken *several decades* with the current feed ban, should now be achieved in approximately ten years."¹³ (Emphasis added.) Thus, the CFIA expects its BSE problem to persist in its cattle herd until around year 2017, even with its upgraded feed ban. Canada has already detected 16 native cases of BSE in its OTM cattle herd, 10 of which were born after the 1997 feed ban, and the most recent of these cases was detected last November. Nine of Canada's BSE-infected cattle met USDA's age requirements to be exported to the United States as they were born after USDA's March 1, 1999, the date after which USDA claims erroneously that the spread of BSE was controlled in Canada.

The CFIA further stated in regard to its previous feed ban, which again is comparable to the current U.S. feed ban, "However, even compliance with the ban's requirements left limited opportunities for contamination during manufacture, transportation and storage. In addition, the accidental misuse of feed on farms with multiple species could not be discounted."¹⁴

The World Organization for Animal Health (OIE) and scientists the world over agree that Canada's heightened BSE risk cannot be effectively mitigated with the basic ruminant-to-ruminant feed ban implemented in both Canada and the U.S. in 1997. The OIE regards the current U.S. feed ban as only a "partial implemented feed ban" that would "allow the risk of recycling and amplification of the BSE agent within the country."¹⁵

Despite urgings of international scientists, Canada resisted any upgrades to its feed ban until after it detected multiple BSE cases in cattle born years after Canada's 1997 feed ban. It is hoped that Canada's July 2007 upgraded feed ban now protects Canadian consumers against the continued spread of BSE from Canadian cattle through the regulatory closure of known transmission routes, including cross-contamination and inadvertent feeding of contaminated cattle parts. It is unthinkable that the FDA is already not affording U.S. consumers with at least this same level of protection against these same Canadian cattle that are entering the United States.

The FDA cannot legitimately argue that its current feed ban implemented in 1997, which is actually weaker than Canada's initial feed ban also implemented in 1997 because it does not ban the feeding of either plate waste or poultry litter to cattle,¹⁶ is any more effective at mitigating Canada's heightened BSE risk within U.S. borders than was Canada's initial feed ban in mitigating Canada's heighten BSE risk in Canada. Nor can FDA ignore the scientific evidence

¹³ Feed Ban Enhancement Questions and Answers, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/anima/feebet/rumin/enhqueste.shtml>.

¹⁴ *Ibid.*

¹⁵ Report of the Meeting of the OIE Scientific Commission for Animal Diseases, International Committee, World Organization for Animal Health (OIE), Paris, France, February 26-28, 2007, at 27.

¹⁶ See 72 Federal Register, at 1106, col. 2.

that overwhelmingly shows that the current U.S. feed ban is insufficient to mitigate the heightened risk of BSE amplification and spread associated with OTM cattle imported from Canada. These higher-risk OTM Canadian cattle are entering the U.S. at the rate of several thousand per week, are being commingled in the U.S. cattle herd where some would be expected to die, and are entering both the U.S. food system as well as the U.S. animal feed system. The U.S. already is accepting Canada's higher BSE risk *without* even the minimal protection of an upgraded U.S. feed ban similar to Canada's new feed ban, which Canada *hopes* is capable of addressing the heightened BSE risk in Canadian cattle.

C. The FDA Has An Absolute Duty to Immediately Protect the U.S. From the Known Risk of BSE

The FDA cannot bury its head in the sand and pretend the upgraded feed ban contained in the 2008 BSE final rule is not urgently needed to attempt to mitigate the increased BSE risk associated with the importation of millions of Canadian cattle. In fact, the FDA already has failed to timely implement an upgraded feed ban, which should have been implemented *before* USDA began to expose U.S. consumers and the U.S. cattle herd to Canada's heightened BSE risk. In fact, because the effectiveness of the upgraded feed ban in Canada, which is intended to halt the amplification and spread of the heightened level of BSE infectivity circulating in Canadian cattle, remains uncertain, the U.S. should not be exposing the U.S. to higher-risk Canadian cattle until Canada can scientifically demonstrate that its upgraded feed ban has eradicated BSE from its cattle herd.

The FDA has an absolute responsibility to protect the health and safety of U.S. consumers and the U.S. cattle herd against this foreign animal disease that is always fatal and believed to be transferable to humans. The FDA must break away from the manipulative actions by the corporate-controlled, self-serving trade associations that have caused both FDA and USDA to endanger the health and safety of U.S. consumers and the U.S. cattle herd by exposing them to an unnecessary and avoidable risk of BSE.

If USDA does not *immediately* eliminate the source of this heightened BSE risk by prohibiting the importation of Canadian cattle, FDA has no choice but to *immediately* implement the 2008 BSE final rule to at least *attempt* to begin mitigating this heightened risk. There are no responsible alternatives.

III. ADDRESSING ECONOMIC IMPLICATIONS

The FDA asserts in the *Federal Register* that even after a one-year period to prepare for the new FDA feed ban rule, some affected persons may not be in compliance on April 27, 2009, implying that the FDA feed ban rule may present a logistic and/or economic challenge for such persons. However, any logistic or economic challenge that may be experienced by these persons is far outweighed by the urgent need to address the significantly increased risk that U.S. consumers and the U.S. cattle herd already are continuously subjected to due to the continued importation of live Canadian cattle, which were first reintroduced into the U.S. in mid-2005 (cattle under 30 months (UTM) of age); and, their introduction was subsequently expanded after the November 19, 2007, implementation of the USDA's rule that allows higher-risk OTM cattle

from Canada into the United States. Both these higher-risk UTM and OTM cattle continue to enter the U.S. animal feed supply.

Moreover, any logistic or economic challenge that such persons may be subjected to also is far outweighed by the economic losses that continue to accrue to the hundreds of thousands of U.S. cattle producers whose cattle prices remain depressed because important U.S. export customers consider the U.S. practice of importing live Canadian cattle too risky to ensure the safety of U.S. beef. The U.S. International Trade Commission (USITC) estimated that BSE-related export restrictions caused U.S. cattle producers to lose \$1.1-1.4 billion in annual revenues from 2004 through 2007.¹⁷ It also found that the greatest losses were attributed to restrictions imposed by Japan and South Korea,¹⁸ and “[c]ompared with 2003 levels, the value of U.S. beef exports to Korea lost due to BSE restrictions during 2004–07 could be as high as \$3 billion.”¹⁹

A. Failure to Immediately Implement the FDA Enhanced Feed Ban Rule Likely Would Further Delay the Removal of Beef Import Restrictions Imposed by South Korea – One of the Two Most Important U.S. Beef Export Markets.

According to the USITC, the U.S. entered an agreement with South Korea – the second largest U.S. beef export market in 2003²⁰ – to lift restrictions on U.S. OTM beef in two stages, provided the U.S. undertook certain steps to enhance its BSE mitigation measures. South Korea first agreed to open its market to U.S. UTM beef (stage one) and then further agreed to lift restrictions on U.S. OTM beef after the U.S. published the FDA’s enhanced feed ban rule (stage two).²¹ Though the FDA published its enhanced feed ban rule on April 25, 2008, its effective date was delayed until April 27, 2009. South Korea has not yet lifted its OTM restrictions on U.S. beef, presumably because the FDA feed ban is not yet implemented. Instead, exports to South Korea are subject to a “transitional private sector initiative” by U.S. beef exporters to export only beef from UTM cattle until Korean consumer confidence in U.S. beef recovers.²² Consumers in South Korea consider the risk of BSE in U.S. beef to be “very high.”²³ And, media reports indicate the South Korea had delayed the resumption of U.S. beef imports because it was concerned that the U.S. is commingling Canadian beef with U.S. beef.²⁴ Further, South Korea continues to completely ban any beef produced in Canada from Canadian cattle.²⁵

Any delay in the implementation of the enhanced feed ban rule would further exacerbate the United States’ inability to fully restore access to lost export markets. This is most certainly

¹⁷ See Global Beef Trade: Effects of Animal Health, Sanitary, Food Safety, and Other Measures on U.S. Exports, U.S. International Trade Commission, USITC Publication No. 4033, September 2008, at 12-1.

¹⁸ See *id.*, at xvii.

¹⁹ See *id.*, at 6-10.

²⁰ See *id.*, at 6-1.

²¹ See *id.*, at 6-13, fn 61.

²² See *id.*, at 6-2; see also Export Requirements for the Republic of Korea, U.S. Food Safety and Inspection Service, KS-84, January 12, 2009, available at http://www.fsis.usda.gov/regulations_&_policies/Republic_of_Korea_Requirements/index.asp.

²³ See *id.*, at 6-5.

²⁴ “Delay in U.S. Beef Exports to South Korea Will Be Resolved ‘Within Weeks,’ USDA Says,” *Daily Report for Executives*, BNA, Inc., No. 113, Tuesday June 13, 2006, at A-19.

²⁵ See Chapter 11.7.3.2 Import Prohibitions or Restrictions, Meat Hygiene Manual of Procedures, Canadian Food Inspection Agency, available at <http://www.inspection.gc.ca/english/fssa/meavia/man/ch11/coupay/kor-core.shtml>.

the case with South Korea, and likely the case with many more markets given the world's knowledge that the U.S. has assumed a higher BSE risk from Canada while continuing to maintain a weaker BSE feed ban than any other country in the world where BSE has been found.²⁶

B. U.S. Beef Remains Subject to Severe BSE-Related Export Restrictions that Are Not Likely to be Lifted Until the U.S. Strengthens its Resistance to Canada's Higher BSE Risk

The following chart depicts BSE restrictions by major beef importing countries:

BSE RESTRICTIONS ON U.S. BEEF IMPOSED BY MAJOR BEEF IMPORTING COUNTRIES

Country	Age Restriction	Specified Risk Material (SRM) Definition	Commodity Restrictions
Japan	20 months or younger	Head (excluding tongue and cheek meat), palatine and lingual tonsils, spinal cord and dura matter, distal ileum, vertebral column, and dorsal root ganglia.	No ground beef, processed beef, head meat, finely textured beef, or mechanically separated meat.
Korea	Under 30 months	Skull, brain, eyes, distal ileum, tonsils, spinal cord, vertebral column.	Cattle must be born and raised in the United States, or imported from a country deemed eligible by the Korean government to export beef or beef products to Korea, or raised in the United States for at least 100 days. Traceback records must be maintained for at least 2 years. No mechanically recovered meat or mechanically separated meat.
Mexico	Under 30 months	Skull, brain, eyes, tonsils, spinal cord, and small intestine.	No ground meat, feet, sweetbreads, Weasand meat, or head meat.
Hong Kong	Under 30 months	Skull (including brain, eyes and trigeminal ganglia), tonsils, spinal cord, dorsal root ganglia (with the vertebral column) and intestine.	No ground beef, bone-in beef, edible offal, or beef derived from advanced meat recovery systems.

Source: USITC Publication 4033, September 2008, 4-9.

C. U.S. Cattle Producers Continue to Suffer Substantial Financial Losses Due to the United States' Failure to Properly Protect the U.S. Cattle Herd and U.S. Beef Supply Against the Risk of BSE

USDA predicted that U.S. cattle producers would suffer a financial loss of over \$66 million in 2008 as a result of importing higher-risk OTM cattle from Canada.²⁷ This prediction was based on USDA's estimate that only 75,000 OTM Canadian cull cattle (63,000 cows and 12,000 bulls) would be imported into the U.S. in 2008.²⁸ However, the U.S. actually imported well over twice this number, nearly 200,000 OTM cull cattle (156,395 cows and 43,147 bulls) from Canada in 2008.²⁹ Thus, the actual financial losses experienced by U.S. cattle producers,

²⁶ Canada upgraded its feed ban in July 2007 and the feed bans of the European Union and Japan ban a wider range of ruminant material from all animal feed.

²⁷ See 72 Federal Register, at 53356, col. 1, 2.

²⁸ See 72 Federal Register, at 53355, col. 2.

²⁹ See Canadian Live Cattle Imports Into the U.S. by Destination, Data for w/e 12/27/08, U.S. Department of Agriculture, Agricultural Marketing Service, Report WA_LS637, December 31, 2008, available at http://search.ams.usda.gov/mndms/2008/12/WA_LS63720081231.TXT.

as a result of the increased supplies of higher-risk OTM Canadian cull cattle that entered the U.S. market in 2008, likely were well over what USDA projected. Also, this estimated loss does not include the costs to U.S. cattle producers for the UTM cattle that began entering the U.S. in mid-2005. And, these losses would be expected to continue. Neither USDA nor FDA have done anything to mitigate this loss, including making even minimal improvements to the U.S. feed ban to enhance export opportunities that would have helped alleviate the additional supply of beef resulting from these additional supplies of higher-risk slaughter cattle.

Total compliance costs with the FDA enhanced feed ban rule are expected to be \$64.0-80.5 million per year.³⁰ Based on the foregoing discussion, these compliance costs are much lower than the continuing losses faced by independent U.S. cattle producers directly caused by the premature relaxation of U.S. border protections needed to safeguard the U.S. from the introduction and spread of BSE. There is no justifiable reason to delay the new FDA feed ban.

IV. CONCLUSION

The FDA has a duty to protect United States consumers and the U.S. cattle herd from the known, increased risk of BSE resulting from the ongoing importation of higher-risk Canadian cattle. The current U.S. feed ban, which is weaker than the feed ban initially implemented in Canada and found to be insufficient to halt the amplification and spread of Canada's level of BSE infectivity, is likewise inadequate to prevent the amplification and spread of the BSE that is *expected* to be continually introduced into the United States from Canadian cattle.

R-CALF USA believes that USDA acted recklessly and irresponsibly by allowing higher-risk Canadian cattle to enter the United States even before the U.S. implemented such basic measures as an enhanced feed ban to at least attempt to reduce that higher risk, and before it conducted a scientific investigation to determine if Canada's upgraded feed ban was even meeting Canada's expectations for BSE eradication. Under present circumstances the U.S. remains exposed to a heightened BSE risk from Canadian cattle and FDA has no choice but to immediately implement the enhanced feed ban to at least attempt to reduce the increased risk of BSE. Under no circumstances should FDA delay implementation of the enhanced feed ban while higher-risk Canadian cattle are continuing to enter the United States.

R-CALF USA appreciates this opportunity to submit its comment on this important matter and we trust that FDA will responsibly decide to put the health and safety of U.S. consumers and the U.S. cattle herd ahead of the self-interested corporations and their trade associations that continue to ignore the very real and long-term risks associated with BSE.

Sincerely,



R.M. Thornsberry, D.V.M.
President, R-CALF USA Board of Directors

³⁰ See 73 Federal Register, at 22737, col. 1.