CENTER FOR FOOD SAFETY

INSTITUTE FOR AGRICULTURE AND TRADE POLICY

July 22, 2013

Via First Class Mail and Uploaded to www.regulations.gov

MARGARET A. HAMBURG, M.D. In her official capacity as,
Commissioner of the Food and Drug Administration

DOCKETS MANAGEMENT BRANCH
Food and Drug Administration
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville, MD 20852

RE: Records Supplementing FDA Docket No. FDA-2013-P-0351/P

Dear Commissioner Hamburg and Dockets Management Branch Coordinator:

Indexed below and submitted herewith to the Food and Drug Administration by the Center for Food Safety (CFS) and the Institute for Agriculture and Trade Policy, 501(c)(3) nonprofit organizations, are records supplementing CFS and IATP's "Citizen Petition to Prohibit or Enjoin the Use of Antibiotics in the Production of Distillers Grains Sold as Animal Feed for Food Producing Animals", FDA docket number FDA-2013-P-0351/CP1. These records are submitted *in addition to records #1 through #237 filed with the petition on March 20, 2013.* Kindly file these additional records with the Petition and include in FDA's review of the Petition.

238. Wells, J., Shackelford, S.D., Berry, E.D., Kalchayanand, N., Bosilevac, J.M., Wheeler, T.L. 2011. "Impact of reducing the level of wet distillers grains fed to cattle prior to harvest on prevalence and levels of Escherichia coli O157:H7 in feces and on hides." *Journal of Food Protection.* 74, no. 10 (2011):1611-1617.

239. Varel, V.H., Wells, J., Berry, E.D., Miller, D.N. "Manure Odor Potential and Escherichia coli Concentrations in Manure Slurries of Feedlot Steers Fed 40% Corn Wet Distillers Grains." *Journal of Environmental Quality.* 39, no. 4 (2010): 1498-1506.

240. Varel, V.H., Wells, J., Berry, M.J., Spiehs, D.N., Miller, C.L., Ferrell, S.D., Shackelford, S.D., Koohmaraie, M. "Odorant production and persistence of Escherichia coli in manure slurries from cattle fed zero, twenty, forty, or sixty percent wet distillers grains with solubles." *Journal of Animal Science.* 86, no. 12 (2008): 3617-3627

241. Durso, L.M., Wells, J., Harhay, G.P., Rice, W.C., Kuehn, L., Bono, J.L., Shackelford, S., Wheeler, T., Smith, T.P.L. "Comparison of bacterial communities in faeces of beef cattle fed diets containing corn and wet distillers' grain with solubles." *The Society for Applied Microbiology.* 55, no. 2 (2012): 109-114.

242. James Wells (Principal Investigator), USDA-ARS, U.S. Meat Animal Research Center, Research Project Summary Outline – Interim Report, "Effects of Level of Wet Distillers Grain Fed on Pathogen Load of Calf-fed Steers" (January 31, 2008).

243. James Wells (Principal Investigator), USDA-ARS, U.S. Meat Animal Research Center, Research Project Summary Outline – Final Report, "Effects of Level of Wet Distillers Grain Fed on Pathogen Load of Calf-fed Steers" (June 23, 2008).

244. Wells, J., Shackelford, S.D., Berry, E.D., Kalchayanand, N., Guerini, M.N., Varel, V.H., Arthur, T.M., Bosilevac, J.M., Freetly, H.C., Wheeler, T.L., Ferrell, C.L., Koohmaraie, M. "Prevalence and Level of Escherichia coli O157:H7 in Feces and on Hides of Feedlot Steers Fed Diets With or Without Wet Distillers Grains with Solubles." *Journal of Food Protection*. 72, no. 8 (2009):1624-1633.

245. Excerpt, Wells, J., Shackelford, S.D., Berry, E.D., Kalchayanand, N., Guerini, M.N., Varel, V.H., Arthur, T.M., Bosilevac, J.M., Freetly, H.C., Wheeler, T.L., Ferrell, C.L., Koohmaraie, M. "Prevalence and Level of Escherichia coli O157:H7 in Feces and on Hides of Feedlot Steers Fed Diets With or Without Wet Distillers Grains with Solubles." *Journal of Food Protection*. 72, no. 8 (2009):1624-1633.

246. Jim Wells (Project Leader), USDA-ARS, U.S. Meat Animal Research Center, Experimental Outline, Experiment Number 5438-32000-026-03, "Effect of wet distillers grain diet on feedlot performance, zoonotic pathogen prevalence and persistence, and carcass quality of feedlot steers." (Updated 8/22/2007)

247. Steven Shackelford (Project Leader), USDA-ARS, U.S. Meat Animal Research Center, Experimental Outline, Experiment Number 5438-31430-004-04, "Strategies to minimize the impact of wet distillers grains on marbling and E. coli O157:H7."

248. Elaine D. Berry (Lead Scientist), USDA-ARS, Meat Safety and Quality Research Unit, Project Plan, NP 108 – Food Safety, Old ARS Research Project Number: 5438-32000-026-00D, "Prevention of Pathogen Transmission from Animal Manure to Food, Water, and Environment" (September-December 2010).

249. Progress Report, AD-421 CRIS, Project Number 5438-42000-013-14T, "Effects of Distillers Grains on Escherichia coli O157:H7 in Finishing Feedlot Cattle" (10/29/2007 to 5/31/2007).

250. Report of Progress (AD-421), Agricultural Research Information System, USDA-ARS, Meat Safety and Quality Research Unit, Project Number 5438-32000-026-00D, "Prevention of Zoonotic Pathogen Transmission from Animal Manure to Human Food," Period Covered: 10/2007 to 9/2008 (Published 8/13/2008).

251. Report of Progress (AD-421), Agricultural Research Information System, USDA-ARS, Meat Safety and Quality Research Unit, Project Number 5438-32000-026-00D, "Prevention of Zoonotic Pathogen Transmission from Animal Manure to Human Food," Period Covered: 10/2008 to 9/2009 (Published 7/24/2009).

252. Report of Progress (AD-421), Agricultural Research Information System, USDA-ARS, Meat Safety and Quality Research Unit, Project Number 5438-32000-026-00D, "Prevention of Zoonotic Pathogen Transmission from Animal Manure to Human Food," Period Covered: 10/2009 to 9/2010 (Published 7/30/2010).

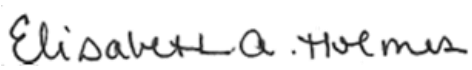
253. Report of Progress (AD-421), Agricultural Research Information System, USDA-ARS, Meat Safety and Quality Research Unit, Project Number 5438-32000-026-00D, "Prevention of Zoonotic Pathogen

Transmission from Animal Manure to Human Food," Period Covered: 10/2010 to 9/2011 (Published 9/19/2011).

Please call me at (415) 826-2770 or email me at eholmes@centerforfoodsafety.org should you have questions concerning the enclosed.

Thank you for your prompt attention to this matter.

Sincerely,



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Enclosures