

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

FARM-TO-CONSUMER LEGAL)	
DEFENSE FUND, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 5:10-cv-4018-MWB
)	
KATHLEEN SEBELIUS, Secretary,)	
United States Department of Health)	
and Human Services, et al.,)	
)	
Defendants.)	

PLAINTIFFS' OCTOBER 2010 STATUS REPORT

Pursuant to the Court's Order of September 17, 2010 (doc. #29), the Plaintiffs hereby submit their status report.

Plaintiffs inquired of the Defendants whether they wished to file a joint status report and were informed that Defendants would be filing their own status report. Consequently, Plaintiffs are filing their own status report after being unable to obtain Defendants' consent to file a joint status report.

Plaintiffs state that on October 18, 2010 they forwarded by email attachment to counsel for the Defendants the following documents for Defendants' review:

1. National Institutes of Health, U.S. Department of Health and Human Services, "Get the Facts: An Introduction to Probiotics" published by the National Center for Complementary and Alternative Medicine, January 2007;
2. Nutraingredients.com article, May 14, 2007, "Probiotics could improve premature babies' gut health," related to study titled "Probiotics for

prevention and necrotizing enterocolitis in preterm neonates with very low birth weight: a systematic review of randomized controlled trials" published in *The Lancet*, May 2007, Volume 369, Issue 9573, Pages 1614-1620;

3. Nutraingredients.com article, October 12, 2005, "Probiotics increase protection against autoimmune disease;"
4. Nutraingredients.com article, June 20, 2007, "Probiotics protect against bacterial infection," published in *Proceedings of the National Academy of Sciences*, May 1, 2007, volume 104, Number 18, Pages 7617-7621, "Bacteriocin production as a mechanism for the antiinfective activity of *Lactobacillus salivarius* UCC118;"
5. Nutraingredients.com article, June 12, 2007, "Probiotic supplementation during pregnancy and then for the infants after birth could reduce the incidence of eczema, suggests a new clinical trial from Sweden" published in *Journal of Allergy and Clinical Immunology* (Elsevier), Volume 119, Issue 5, Pages 1174-1180, "Probiotics in prevention of IgE-associated eczema: A double-blind, randomized, placebo-controlled trial;"
6. Nutraingredients.com article, September 26, 2007, "Organic baby cereal incorporates probiotics and omega-3;"
7. "Inverse association of farm milk consumption with asthma and allergy in rural and suburban populations across Europe" published in *Clinical and Experimental Allergy* (2006), 37:661-670;

8. "Influence of organic diet on the amount of conjugated linoleic acids in breast milk of lactating women in the Netherlands" published in the British Journal of Nutrition (2007), 97:735-743;
9. Technical abstract of "Colicins inhibit growth of Escherichia coli 0157:H7 but not salmonella in vitro" published in Journal of Food Protection (2004), 67:2603-2607;
10. Abstract from "Contamination of milk by enterococci and coliforms from bovine faeces" published in Journal of Applied Microbiology, 103 (2007) 1393-1405;
11. Freedom of Information Act Request 06-0819 response from the Department of Health and Human Services, May 8, 2007;
12. Letter from Ron Hull and Associates to Sally Fallon, December 28, 2007;
13. Associated Press news article entitled "Bacteria-Contaminated Milk from Massachusetts Dairy is Blamed for 3 Deaths, Miscarriage," January 8, 2008.

Based on conversations between counsel, Plaintiffs understand that FDA will be reviewing the administrative record it generated in support of the promulgation of 21 C.F.R. 1240.61, which was issued final in 1987, when attempting to answer the questions ante posed by the Court in its Order. Plaintiffs wish for FDA to have current information and data to assist FDA in answering the Court's questions ante. Consequently, Plaintiffs have submitted the above identified documents to FDA for their review. All of these documents are attached hereto as well.

Dated: October 18, 2010

Respectfully submitted,

/s/ DAVID G. COX

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CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2010, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system that will send notification of such filings(s) to the following:

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