

October 21, 2006

Document List for 21 CFR § 10.35 Submission to FDA Public Docket 2004P-0349

Petition for Stay of Decision – Decision Letter Failed To Address Petition Issues¹

1. **Petition for Stay of Action – cover, petition, and supporting review of FDA “SEP 26 2006” letter to CoMeD.** [130 pages in total.]
2. **Appendix A – Review of Fombonne et al. (2006).** [45 pages in total.]
3. **Appendix B –Review of Oct. 2006 FDA_Consumer_magazine’s ‘Influenza: Vaccination Still Best Protection.’** [25 pages in total.]
4. **Appendix C – MSDS Documents.** [7 pages in total.]
5. **Referenced documents not in petition and/or not referenced by FDA in their “SEP 26 2006” “decision” letter to CoMeD date-stamped ‘SEP 26 2006’**
 - 5.1 “Ref. 12”: Amin-Zaki L, Majeed MA, Greenwood MR, Elhassani SB, Clarkson TW, Doherty RA. Methylmercury poisoning in the Iraqi suckling infant: a longitudinal study over five years. *J Appl Toxicol* 1981; **1**: 210-214.
 - 5.2 “Ref. 18”: Parran et al. Effects of Thimerosal on NGF signal transduction and cell death in neuroblastoma cells. *Tox Sci* 2005; **86**(1): 130-140.
 - 5.3 “Ref. 20”: Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *J Am Phys Surg* 2006; **11**(3): 69-74 and the supporting studies referenced therein.
 - 5.4 “Ref. 22”: Ayoub DM, Yazbak FE. Influenza vaccination during pregnancy: A critical assessment of the recommendations of the Advisory Committee on Immunization Practices (ACIP). *J Am Phys Surg* 2006; **11**(1): 41-47.
 - 5.5 “Ref. 24”: Jefferson T, Smith S, Demicheli V, Harnden A, Rivetti A, Di Pietrantonj C. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. *Lancet* 2005; **365**: 773-780.
 - 5.6 “Ref. 26”: Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, Clarkson T. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal. *Environ Health Perspect.* 2005 April 21; **113**(4). 36-page draft “pdf” file.
 - 5.7 “Ref. 27” Sugita M. The biological half-time of heavy metals. The existence of a third “slowest” component. *Int Arch Occup Environ Health* 1978; **41**(1): 25–40.
 - 5.8 “Ref. 29” Stetler HC, Garbe PL, Dwyer DM, Richard R, Facklam RR, Orenstein WA, West GR, Dudley KJ, B. Bloch AB, Outbreaks of group A streptococcal abscesses following diphtheria tetanus toxoid-pertussis vaccination. *Pediatrics* 1985; **75**(2): 299-303.
 - 5.9 “Ref. 34” Hekkens, F. E. An., Polak-Vogelzang, A. A., and Kreeftenberg, J. G. 1983. The antimicrobial effectiveness of some preservatives in inactivated human vaccines. *J Biol Stand* 1983; **9**:277-285.
 - 5.10 “Ref 35” Lowe I, Southern J. The antimicrobial activity of phenoxyethanol in vaccines. *Lett Appl Microbiol* 1994; **18**: 115-116.
 - 5.11 “Ref. 39” Maeda T, Shintani Y, Nakano K, Terashima K, Yamada Y. Failure of inactivated influenza A vaccine to protect healthy children aged 6-24 months. *Pediatr Int* 2004; **46**: 122-125.
 - 5.12 “Ref. 40” Al-Saleh I, El-Doush I, Shinwari N, Al-Baradei R. Does low mercury containing skin-lightening cream (Fair & Lovely) affect the kidney, liver, and brain of female mice? *Cutaneous & Ocular Tox* 2005; **24**: 11-29.
 - 5.13 “Ref. 47” Gosselin NH, Burnet RC, Carrier G, Bouchard M, Feeley M. Reconstruction of methylmercury intakes in indigenous populations from biomarker data. *J Expo Anal Environ Epidemiol.* 29 June 2005; **E-pub** (www.nature.com/jea): 1-11
 - 5.14 “Ref. 55” Geier DA, Geier MR. Early downward trends in neurodevelopmental disorders following removal of Thimerosal-containing vaccines. *J Am Phys Surg.* 2006 Spring; **11**(1): 8-12.
 - 5.15 “Ref. 56” Geier DA, Geier MR. An assessment of downward trends in neurodevelopmental disorders in the United States following removal of thimerosal from childhood vaccines. *Med Sci Monit.* 2006 May 29; **12**(6): CR231-CR239 [Epub ahead of print].
 - 5.16 “Ref. 57” Geier DA, Geier MR. A meta-analysis epidemiological assessment of neurodevelopmental disorders following vaccines administered from 1994 through 2000 in the United States. *Neuro Endocrinol Lett.* 2006 Aug 30; **27**(4), in press. [Epub ahead of print].
 - 5.17 “Ref. 59” Bingham M, Copes R. Thimerosal in vaccines – Balancing the risks of adverse effects with the risk of vaccine-preventable disease. *Drug Safety* 2005; **28**(2): 89-101.
 - 5.18 “Ref. 60” Waly M, Olteanu H, Banerjee R, Choi S-W, Mason JB, Parker BS, Sukumar S, Shim S, Sharma A, Benzecry JM, Power-Charnitsky V-A, Deth RC, **IMMEDIATE COMMUNICATION**, Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal. *Molecular Psychiatry* 2004 January 27: 1-13.

¹ Re: Public Docket: 2004P-0349/PDN1