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May 15, 2006

Acting Commissioner Andrew Von Eschenbach
Associate Commissioner Randy Lutter, Ph.D., Policy
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20847 -- – *via e-mail to Dr. Lutter et al.*

Re: *Moms Against Mercury, et al*., v. *FDA*:
Opportunity for FDA to Stay Sales of Mercury Fillings
Before Petitioners Move Court for Same

Dear Acting Commissioner Von Eschenbach and Associate Commissioner Lutter,

As you know, four nonprofit groups, two state officials, a dentist, and two consumers have petitioned the United States Court of Appeals, DC Circuit, for an order to ban encapsulated mercury amalgam ("silver" fillings). The basis is FDA's abject failure to regulate it: (1) decades of failing to classify mercury amalgam, yet classifying all other (even lesser-used) filling materials; (2) devising a scheme to allow sales without classifying or requiring proof of safety by falsely equating this capsule containing 50% toxic mercury with a classified device that has no mercury, is not a capsule, and isn't even ready to be used as a filling material; (3) using this sham classification scheme on a "temporary" basis for two decades while continuing to make empty promises to classify amalgam; (4) allowing sales, under this classification scheme, of a product that (because it contains mercury while being defined as having no mercury) is adulterated, misbranded, or both; and (5) refusing to do an environmental impact statement of the major source of mercury in America's wastewater.

As you know or should know, mercury amalgams are no longer needed in oral health care. Modern dentists no longer implant them – they are not needed for any kind of cavity, child or adult. The pro-mercury dentists use amalgam for quick profit-taking – it is easier work for assembly-line dentistry.

FDA's decision to allow mercury amalgam sales with neither proof of safety nor a classification became unglued via its order of April 3. At last, FDA recognized the neurotoxicity issue involved with the mercury in dental fillings. **Recognizing the issue of neurotoxicity acknowledges this unclassified device is substantially different from a non-mercury, non-encapsulated alloy**.

To allow sales of mercury amalgam is no longer legally justified. Lacking both a classification and a bona fide substantial equivalence means mercury amalgam is now in a regulatory netherworld. (Nor can FDA staff get their story straight on how encapsulated mercury amalgam is classified: when challenged by an astute consumer from Georgia, Dr. Mary Susan Runner and two of her aides declared, in succession: (1) encapsulated amalgam is already classified, as one device; (2) no, we mean encapsulated

amalgam is already classified, but as a dual device, and (3) no, we mean encapsulated amalgam is not yet classified, with the decision to classify "on hold.")

We ask you to stop the sale of encapsulated mercury amalgam pending (1) classification, (2) manufacturer proof of safety, and (3) an environmental impact statement. Petitioners would also find acceptable – and will not move for a stay – should FDA implement a ban on mercury fillings for pregnant women and children under six.

Please reply by 12 noon on Thursday, May 25, 2006. If you fail to answer or if you reply in the negative, under Rule 18, "Stay Pending Review," Circuit Rules of the Court of Appeals, D.C. Circuit, petitioners intend to move the Court for a stay on the sale of mercury fillings.

Sincerely,

Charles G. Brown

cc: Chief Counsel Sheldon Bradshaw; Acting Associate Commissioner Jason Brodsky