

RE: DOCKET NO. 01N-0067-Against FDA Rule

7426 Rhoads St.
Phila, Pa 19151-2290
Sept. 7, 2002

Dockets Management Branch-(HFA-305)
Food & Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20057

Dear Sir or Madam:

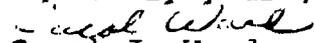
This letter is the 2nd I have sent you concerning your proposed re-classification of mercury amalgam to a class II device. I am very strongly against this reclassification a mercury amalgam is an unstable compound, giving off vapor in the mouth, leeching into the body & blood stream. Further, mercury & saliva form a battery effect in the mouth which stresses the nervous system in susceptible individuals.

I had a life-threatening amalgam-related breakdown at the age of 45 and only began recovering when my amalgams were replaced by composites. I had MS -type symptoms: equilibrium problems, dizziness, numbness of extremities, and visual field problems. As I had my 16 amalgams replaced, I felt my health beginning to return. At the last removal, my visual field went to normal. Later most of it cleared up.

Have you read the 1500 plus Adverse Reaction reports in the FDA files that show the variety of health problems people had and how much they improved after amalgam removal? There is much scientific research, also, which I feel the FDA has ignored. Please consults DAMS website www.amalgam.org for scientific studies.

It takes 1 gr. of mercury, a thermometer full to pollute a lake. Each amalgam filling contains up to 50% mercury and it pollutes the human body. The FDA is ignoring current research about mercury fillings. It ignores the fact that from 1-15% of the population is sensitive to mercury and undermined by it. Mercury is a poison. Mercury amalgams should not be a Class II device. It is time for truth in dentistry and informed consent for the public. Mercury affects the unborn, it flows past the placenta. Experiments have demonstrated this. The FDA should be protecting the public against harm. This is your opportunity to do so- with the proper classification of mercury amalgam fillings.

Sincerely yours,


Carol J. Ward

V. President- DAMS, Inc.

01N-0067

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Docket Number – 01N-0067 – Against FDA Rule

October 12, 2002

Dear FDA,

Per Jennie Bulter's request, I am re-faxing this letter by Carol Ward sent to the FDA on September 7, 2002 so it can be recorded for public record.

**Thank you,
Mary Ann Newell
Manager of the Files for Consumers for Dental Choice**