



MBS:ABKlein  
21-16-488

U.S. Department of Justice  
Civil Division, Appellate Staff  
950 Pennsylvania Avenue, N.W., Rm: 7235  
Washington, D.C. 20530

Tel: (202) 514-1597  
Fax: (202) 514-9405

September 14, 2010

Mr. Mark Langer  
Clerk, United States Court of Appeals  
for the D.C. Circuit  
333 Constitution Ave., N.W., Room 5523  
Washington, D.C.

Re: *Sottera, Inc. v. FDA*, No. 10-5032

Dear Mr. Langer:

Oral argument in this case is scheduled for September 23, 2010, before Circuit Judges Garland, Kavanaugh, and Williams.

This case concerns FDA's regulation of so-called "electronic cigarettes" under the drug and device provisions of the Federal Food, Drug, and Cosmetic Act. We respectfully advise the Court that FDA recently issued warning letters to five electronic cigarette distributors for violations of the FDCA. Links to the warnings letters may be found on the FDA press release, which is available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm225224.htm>. The press release also provides a link to FDA's letter to the Electronic Cigarette Association, which invites electronic cigarette firms to work in cooperation with the agency toward the goal of assuring that electronic cigarettes sold in the United States are lawfully marketed.

Sincerely,

/s/ Alisa B. Klein  
Counsel for FDA *et al.*

**CERTIFICATE OF SERVICE**

I hereby certify that on September 14, 2010, I caused the foregoing letter to be filed with the Court through the CM/ECF system and in hard copy and served on counsel through the CM/ECF system.

/s/Alisa B. Klein

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Alisa B. Klein