



**U.S. Department of Justice**

Office of Consumer Litigation

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September 21, 2007

Mr. Donald R. Earl, *pro se*  
3090 Discovery Road  
Port Townsend, WA 98368-9633  
**Via e-mail to [don-earl@waypoint.com](mailto:don-earl@waypoint.com)**

Re: Earl v. FDA, No. 3:07-cv-05413-BHS (W.D. Wash.)

Dear Mr. Earl:

I write to follow up on your petition for mandamus against the FDA, filed August 9, 2007. We have also received your e-mails of August 28 and September 12, 2007, encouraging an informal resolution to the matter.

Your e-mails suggest litigation is unlikely to provide you a prompt or satisfying response to the concerns raised in your mandamus petition. We will defend this litigation, and expect the FDA to prevail on procedural grounds, prior to any consideration of the merits. Among other things, failing first to seek relief from the FDA through the citizen petition process will prevent the court from reaching the merits of your mandamus petition. (For the requirement of administrative exhaustion before seeking court relief, see 21 C.F.R. § 10.45(b).) If you are interested in receiving a substantive response from the FDA to the concerns expressed in your mandamus petition, the method for doing so is a "citizen petition" addressed to the FDA.

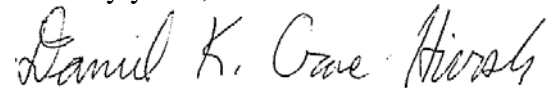
The citizen petition process is described on the FDA's website at <http://www.fda.gov/opacom/backgrounders/voice.html#petitions>. The detailed regulations governing the process are in Title 21 of the Code of Federal Regulations, [Sections 10.30](#), [10.33](#), and [10.35](#).

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Page 2 of 2

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If you decide to file a citizen petition, we would recommend including the level of specific detail in your mandamus petition, rather than simply making blanket assertions of wrongdoing or misconduct.

Sincerely yours,

A handwritten signature in black ink that reads "Daniel K. Crane-Hirsch". The signature is written in a cursive style with a large initial 'D' and 'C'.

Daniel K. Crane-Hirsch  
Trial attorney

cc: Thomas S. Woods, Assistant U.S. Attorney  
Shoshana Hutchinson, Attorney, FDA Office of Chief Counsel