



U.S. Department of Justice

Office of Consumer Litigation

Post Office Box 386
Washington, D.C. 20044-0386

Telephone: (202) 616-8242
Telecopier: (202) 514-8742

July 16, 2008

The Hon. Leonard Green
Clerk of Court
U.S. Court of Appeals for the Sixth Circuit
540 Potter Stewart U.S. Courthouse
100 E. Fifth Street
Cincinnati, OH 45202-3988
Via FedEx

RE: *CareToLive v. von Eschenbach*, No. 07-4465 (6th Cir. oral argument set for July 29, 2008)

Dear Mr. Green:

Pursuant to Fed. R. App. P. 28(j), I write on behalf of defendants-appellees to advise the Court that a Proposed Rule discussed in our merits brief has now been issued (with modifications not pertinent to this appeal) as a Final Rule, *Applications for Approval to Market a New Drug*, 73 Fed. Reg. 39,588 (July 10, 2008) (copy attached).

Our merits brief and the lower court both cited and quoted the 2004 Proposed Rule. *Applications for Approval to Market a New Drug*, 69 Fed. Reg. 43,351 (July 20, 2004), *discussed in Appellees' Br.* at 7-8, 26 (quoting lower court decision), 32 n.10 (quoting lower court decision).

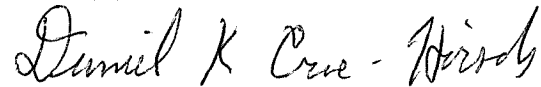
The Proposed Rule explained the "complete response letter" (CR letter) procedure used when responding to biological license applications (BLAs), and indicated that FDA intended to codify the practice. 69 Fed. Reg. at 43,352 (referring to proposed 21 C.F.R. § 601.3).

The Final Rule issued last week does so. 73 Fed. Reg. at 39,598 (response to comments on "Complete Response Letters for BLAs"), 39,605 ("Impact of the Final Rule"), 39,611 (promulgating 21 C.F.R. § 601.3).

The Hon. Leonard Green
July 16, 2008
Page 2 of 2

We would appreciate your distributing this letter to the panel. A copy of the Final Rule is enclosed.

Sincerely yours,



Daniel K. Crane-Hirsch
Trial attorney

Enclosure: *Applications for Approval to Market a New Drug*, 73 Fed. Reg. 39,588 (July 10, 2008)

cc:

Mark T. D'Alessandro
Assistant United States Attorney
U.S. Attorney's Office for the Southern District of Ohio
303 Marconi Blvd., Suite 200
Columbus, OH 43215
Via e-mail to Mark.DAlessandro@usdoj.gov

Kerry M. Donahue
Bellinger & Donahue, Attorneys at Law
6295 Emerald Parkway, Suite 100
Dublin, OH 43016
Via e-mail to BeDonWahoo@aol.com