



**FOR IMMEDIATE RELEASE**

**June 30, 2005**

**WLF CALLS ON DDMAC TO WITHDRAW  
WARNING LETTER ON VISIONBLUE  
(*"DDMAC Watch" Program*)**

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a warning letter sent to Dutch Ophthalmic USA (DO) on June 28, 2005 regarding DO's allegedly improper promotion of VisionBlue on DO's web site. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate in that FDA has never issued any guidance on internet promotion of prescription drugs, despite its promises to do so.

WLF's letter was sent in connection with WLF's recently inaugurated "DDMAC Watch" program. WLF has determined that DDMAC has been using letters to industry to advance questionable legal theories and request remedial actions that the agency could not require under the law. Under the DDMAC Watch program, when DDMAC sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF sends a letter of our own back to DDMAC identifying the specific ways in which this is so.

DDMAC's letter to DO alleged that DO violated federal drug laws by including information on its website about VisionBlue, a tissue staining agent for use as a medical aid in ophthalmic surgery. DDMAC alleged that the web site lacked risk information about VisionBlue. WLF's response took particular issue with DDMAC's demand that DO disseminate "corrective" promotional messages; WLF noted that FDA lacks statutory authority to require "corrective" messages, and that in any event such a demand violates the First Amendment.

WLF is a public interest law and policy center with supporters in all 50 states. WLF for many years has been actively involved in efforts to decrease federal government restrictions on the flow of truthful information about FDA-approved drugs and medical devices, and to limit the circumstances under which the government may compel individuals and companies to speak against their will.

\* \* \*

For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's letter will soon be posted on its web site, [www.wlf.org](http://www.wlf.org).