

**FOR IMMEDIATE RELEASE****August 25, 2005**

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON NIPENT (*"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 SuperGen Inc. on August 18, 2005 regarding SuperGen's allegedly improper promotion of Nipent in connection with a mechanism of action (MOA) booth panel and handout. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate in that FDA faulted SuperGen for failing to include any risk information, even though FDA acknowledged that SuperGen's promotional materials were accompanied by the package insert -- which includes *all* pertinent risk information.

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 SuperGen alleged that SuperGen violated federal drug laws by improperly promoting Nipent, a drug approved for treating certain types of leukemia. DDMAC alleged that the promotional material lacked risk information and made an unsubstantiated claim about Nipent. WLF's response took particular issue with DDMAC's demand that SuperGen 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.

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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.