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FOR IMMEDIATE RELEASE **February 10, 2006**

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON M.V.I.-12

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a letter sent to Mayne Pharma (USA), Inc. on February 1, 2006 regarding Mayne Pharma's allegedly improper promotion of M.V.I.-12. DDMAC alleged that a promotional mailer for Mayne Pharma was false and misleading because it omitted important risk information regarding the drug. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because Mayne Pharma included all necessary risk information in the "brief summary" portion of the advertisement. WLF argued that there is no requirement that a manufacturer repeat that same risk information in the "creative" portion of the advertisement.

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 alleged that Mayne Pharma violated federal drug laws by omitting "important risk information" in its advertisement for M.V.I.-12, a multi-vitamin infusion without Vitamin K. WLF's response took particular issue with DDMAC's demand that Mayne Pharma 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.