

**FOR IMMEDIATE RELEASE**

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## **WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON NEUTROSPEC ("DDMAC Watch" Program)**

The Washington Legal Foundation (WLF) this week called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a letter sent to Palatin Technologies, Inc. on February 16, 2006 regarding Palatin's allegedly improper promotion of NeutroSpec. DDMAC alleged that exhibit panels for NeutroSpec, which were displayed at an April 2005 medical meeting, were false and misleading because they omitted important risk information and used the terms "rapid" and "simple" in connection with use of the drug. WLF's letter to DDMAC alleged that DDMAC's actions did not constitute an appropriate use of limited agency resources -- given that the promotional material at issue has not been used in many months and NeutroSpec is no longer being marketed. WLF questioned why DDMAC is only now issuing its letter, 10 months after the display of the exhibit panels in question.

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 Palatin violated federal drug laws by displaying exhibit panels that failed to provide adequate risk information about NeutroSpec, a radioactive drug that has proven effective in diagnosing appendicitis. WLF's response took particular issue with DDMAC's issuance of an untitled letter in the absence of evidence that NeutroSpec has harmed any patients. WLF said that DDMAC must be aware that plaintiffs' lawyers will use the letter to gin up unwarranted lawsuits.

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](http://www.wlf.org).