WLF Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

FOR IMMEDIATE RELEASE **May 1, 2007**

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTERS ON CIPRODEX, LEVULAN

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw warning letters sent on April 20 to Alcon Laboratories, Inc. (regarding Alcon's allegedly improper promotion of Ciprodex) and to DUSA Pharmaceuticals, Inc. (regarding DUSA's allegedly improper promotion of Levulan Kerastick). DDMAC alleged a retail sales sheet for Ciprodex and an advertisement for Levulan were false and misleading because they failed to disclose all risk information and made unsubstantiated superiority claims. WLF's letter to DDMAC alleged that both of DDMAC's letters were inappropriate, because they characterized promotional materials as misleading without a sufficient empirical basis and inappropriately faulted references to legitimate scientific studies.

WLF's letters were sent in connection with WLF's "DDMAC Watch" program, which is approaching its second anniversary. 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.

One of DDMAC's letters alleged that an Alcon retail sales sheet and a sales aid improperly claimed that Ciprodex, which is approved for treatment of certain infections, was superior to competing products. WLF responded that DDMAC lacked any empirical basis for asserting that readers of certain language in the sales aid would think that Alcon was claiming superiority, and that nothing in that language readily indicates that Alcon was making such a claim. WLF also responded that DDMAC acted improperly in faulting Alcon for citing a study that supported its "less severe pain" claim.

DDMAC's second letter alleged that DUSA's advertisement improperly claimed that Levulan, which is approved for treatment of actinic keratosis ("AK," a type of precancerous lesion), was superior to previously available products and was effective in treating *all* forms of AK. WLF again responded that DDMAC lacked any empirical basis for asserting that readers would think that DUSA was claiming that Levulan had been approved for treating the most severe forms of AK. WLF also charged that DDMAC violates the First Amendment and administrative law when, as here, it seeks to prohibit a

manufacturer from saying anything about the results of a study on patient preferences -- particularly in light of FDA's failure to release any guidance document setting forth standards for consumer preference surveys.

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 government restrictions on the flow of truthful information about FDA-approved drugs and medical devices.

* * *

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.