

Food and Drug Administration Rockville MD 20857

FEB 7 2007

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Donald J. Popeo Washington Legal Foundation 2009 Massachusetts Avenue, N.W. Washington, DC 20036

Docket Number: 2006P-0319/CP1

Dear Mr. Popeo:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 11, 2006. Your petition requests that FDA undertake a comprehensive review of Agency practices and policies relating to prescription drug advertising and promotional labeling for consistency with its statutory authority and with the First Amendment.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Randall W. Lutter, Ph.D. Associate Commissioner for Policy and Planning