DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 4 2007

Rec'd 6/7/07

Charles E. Weber
1908 Country Club Road
Hendersonville, NC 28739

Re: Docket No. 2006P-0508/CP1

Dear Mr. Weber:

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 December 5, 2006. Your petition requests that FDA "make 2 to 5 milligram pills of naltrexone to have an over the counter status."

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0508

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