DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

MAY 22 2014

Frederick S. Mayer, R.Ph., M.P.H., President
Pharmacists Planning Service, Inc.
101 Lucas Valley Road, Suite 384
San Rafael, CA 94903

Re: Docket No. FDA-2013-P-1606

Dear Mr. Mayer:

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 November 25, 2013. Your petition requests, among other things, that the Agency require the reformulation of all hydrocodone-containing schedule II drugs to include abuse-deterrent technologies.

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 requests.

Sincerely,

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