DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 12, 2013

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

Dear Mr. Mayer:

Your petition to the Food and Drug Administration requesting the Agency to issue a federal regulation to make regulatory decisions regarding the reformulation with abuse-deterrant technology of the two opioid drug products, hydrocodone bitartrate ER and hydrocodone/acetaminophen as well as implementing a standard of practice (SOP) for prescription monitoring programs, was received by this office on 11/26/2013. It was assigned docket number FDA-2013-P-1606/CP1, and it was filed on 12/12/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)