



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 10, 2013

Peter R. Mathers
Jennifer A. Davidson
Kleinfeld, Kaplan and Becker, LLP
1140 Nineteenth Street, N.W.
Washington, D.C. 20036-6606

Dear Mr. Mathers:

Your petition to the Food and Drug Administration on behalf of Rhodes Technologies, requesting FDA to take actions described in the petition with respect to 14-hydroxycodone impurity in oxycodone HCl API approved by FDA for use in drug products, was received by this office on 04/10/2013. It was assigned docket number FDA-2013-P-0425/CP1, and it was filed on 04/10/2013. 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,

A handwritten signature in cursive script, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)