



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 16, 2013

Arthur Bedrosian, President and CEO
Lannett Company, Inc.
9000 State Road
Philadelphia, PA 19136

Dear Mr. Bedrosian:

Your petition to the Food and Drug Administration requesting the Agency for a determination that ANDAs may be submitted for Hydromorphone Hydrochloride tablets, 1 mg (scored tablets) and Hydromorphone Hydrochloride Oral Solution, 1 mg per 5 mL, was received by this office on 12/9/2013. It was assigned docket number FDA-2013-P-1636/CP1, and it was filed on 12/16/2013. 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
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)