DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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August 5, 2013

Joan Janulis
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Dear Ms. Janulis:

Your petition to the Food and Drug Administration on behalf of a client requesting to declare that the drug product, Hydrocodone Bitartrate and Acetaminophen Tablets USP, 2.5 mg/300 mg is suitable for consideration in an Abbreviated New Drug Application (ANDA), was received by this office on 8/05/2013. It was assigned docket number FDA-2013-P-0946/CP1, and it was filed on 8/05/2013. 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)