DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

July 10, 2013

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

Re: This is a correction to the acknowledgement letter of 7/3/2013

Dear Ms. Janulis:

Your petition to the Food and Drug Administration requesting to declare that Hydrocodone Bitartrate and Acetaminophen Tablets USP, 4mg/300 mg, 6 mg/300 mg and 8 mg/300 mg are suitable for submission as an abbreviated new drug application (ANDA), was received by this office on 07/03/2013. It was assigned docket number FDA-2013-P-0813/CP1, and it was filed on 07/03/2013. 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,

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

FDA-2013-P-0813 CR