



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 5, 2013

Joan Janulis
Vice President
Lachman Consultant Services, Inc.
Consultants to the Pharmaceutical and Allied Industries
1600 Stewart Avenue
Westbury, NY 11590

Dear Ms. Janulis:

Your petition to the Food and Drug Administration requesting that FDA declare that Tramadol Hydrochloride 37.5 mg and Acetaminophen 300 mg Tablets, is suitable for submission as an Abbreviated New Drug Application ("ANDA"), was received by this office on 06/05/2013. It was assigned docket number FDA-2013-P-0675/CP1, and it was filed on 06/05/2013. 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,

A handwritten signature in cursive script, reading "Gloria Ortega", is written over a horizontal line.

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