DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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September 16, 2013

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

Dear Ms. Janulis:

Your petition to the Food and Drug Administration requesting a determination that Capecitabine Tablets, 300 mg and 1000 mg, are suitable for submission in an Abbreviated New Drug Application (ANDA), was received by this office on 09/09/2013. It was assigned docket number FDA-2013-P-1126/CP1, and it was filed on 09/09/2013. 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)