DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20852

March 20, 2019

Sharif Ahmed MS, RAC
Principal Consultant
Lachman Consultants
1600 Stewart Ave
Suite 604
Westbury, NY 11590

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug Administration declare that the drug product, Paclitaxel for Injection Suspension, in a 200 mg/vial lyophilized powder is suitable for submission in an ANDA was received by this office on 03/19/2019.

It was assigned docket number FDA-2019-P-1318. 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,

Dynna Bigby

Digitally signed by Dynna Bigby
Date: 2019.03.20 14:38:18 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)