



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

March 2, 2007

Shylah D. Merrick
Director, Regulatory Affairs and Quality Measurement
Sovereign Pharmaceuticals, Ltd.
7590 Sand Street
Fort Worth, TX 76118

Dear Ms. Merrick:

Your petition requesting the Food and Drug Administration to determine that an 505(j)(2)(C) application may be submitted for two strengths of Promethazine Hydrochloride and Hydrocodone Bitartrate Syrup, 6.25 mg/2.5 mg per 5 mL and 6.25 mg/1.67 mg per 5 mL, was received by this office on 03/02/2007. It was assigned docket number 2007P-0076/CP1 and it was filed on 03/01/2007. 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 that reads "Lyle D. Jaffe".

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2007P-0076

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