DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 4, 2006

FILE COPY

Charles R. Nolan, M.D
[redacted]

Dear Dr. Nolan:

Your petition requesting the Food and Drug Administration to withdraw the new drug application (NDA 21-179) for Renagel Tablets (sevelamer hydrochloride) 400 and 800 mg, a treatment for hyperphosphatemia in patients with end-stage renal disease (ESRD), was received by this office on 05/04/2006. It was assigned docket number 2006P-0186 and it was filed on 05/04/2006. 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,

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0186

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