October 30, 1998

NDA 20-926

GelTex Pharmaceuticals, Inc.
Attention: Ms. Martha Carter
Vice President, Regulatory Affairs
Nine Fourth Avenue
Waltham, MA 02451

Dear Ms. Carter:

Please refer to your new drug application (NDA) dated November 3, 1997, received November 3, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Renagel (sevelamer hydrochloride) Capsules, 403 mg.

We acknowledge receipt of your submissions dated December 10 and 19, 1997; and January 21, February 13, March 13, July 16, August 4, September 2 and 30, and October 1(9), 5(2), 8(2), 9(2), 20, and 30, 1998. The user fee goal date for this application is November 3, 1998.

This new drug application provides for the use of Renagel (sevelamer hydrochloride) Capsules for the reduction of serum phosphorus in patients with end stage renal disease who are on hemodialysis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 30, 1998, immediate container and carton labels submitted October 9, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-926." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment made in your October 8, 1998, submission in which Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of the commitment in your

annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments should be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301)827-6392.

Sincerely,

Florence Houn, M.D., M.P.H.
Deputy Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research