DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 23 1998

TRANSMITTED VIA FACSIMILE

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

Re: **NDA 20-926**
Renagel Capsules (Sevelamer HCl)
MACMIS ID # 7205

Dear Ms. Carter:

Reference is made to the Word Wide Web (web) site for GelTex Pharmaceuticals, Inc. (GelTex). GelTex's web site contains two web pages entitled, "Product Pipeline". Included on page one of the Product Pipeline site is, among other information, information on the investigational product, Renagel.[1] DDMAC has determined that this web page is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the regulations promulgated thereunder. Specifically, the information contained on this web page promotes an unapproved new drug.

The regulations promulgated pursuant to the Act, at 21 CFR 312.7 state, among other things, that an investigational new drug may not be promoted as being safe and effective for the uses under investigation.

This web page text makes specific and unsubstantiated claims regarding the safety and efficacy, including comparative claims, of Renagel for a use under investigation. The following are some examples found on the page:

- Current therapies that bind dietary phosphate contain calcium or aluminum, which can cause hypercalcemia and constipation or bone softening and Alzheimer's-like dementia, respectively.

---

[1] http://www.geltex.com/ProductPipeline.html as of 10/23/98

- RenaGel, which uses neither calcium nor aluminum, has shown equivalent efficacy to calcium-based binders and was well tolerated in two Phase III trials completed in February 1997, in patients on kidney dialysis.

- The trials demonstrated that RenaGel significantly reduces serum phosphorus levels without increasing serum calcium levels.

- Recently, the Company initiated a clinical trial in pre-dialysis chronic renal failure patients, potentially expanding the patient population that could benefit from RenaGel.

To address these violations, GelTex should remove the cited information, and all similarly violative information with the same or similar themes, from the GelTex web site immediately upon receipt of this letter. GelTex should submit a written response to DDMAC on or before November 2, 1998, confirming that GelTex has discontinued the dissemination of this information, and the date of discontinuation.

If GelTex has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #7205 in addition to the NDA number. DDMAC reminds GelTex that only written communications are considered official.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Regulatory Review Officer,
Division of Drug Marketing,
Advertising, and Communications