CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020926

ADMINISTRATIVE DOCUMENTS/CORRESPONDENCE

NDA 20-926
Renagel (sevelamer hydrochloride) Capsules
GelTex Pharmaceuticals, Inc.

Date:
10/8/98

CONTACT:
Ms. Martha Carter
781-290-5888

MEMORANDUM OF TELECON

I spoke with Martha Carter, concerning NDA 20-926, Renagel (sevelamer hydrochloride) Capsules. I referred her to the October 1, 1998 correspondence in which GelTex Pharmaceuticals

[redacted]

APPEARS THIS WAY
ON ORIGINAL

[redacted]; therefore, making it a firm commitment. She stated that the firm would send a new Phase 4 commitment letter without the qualifiers.

/S/

Randy Hedin, CSO

APPEARS THIS WAY
ON ORIGINAL

cc: NDA Arch
HFD-510
HFD-510/BSchneider/GTroendle/EGalliers
HFD-511/RHedin/10.20.96/N20926.PH1

Record of Telephone Conversation

NDA 20-926
Renagel
GelTex
Friday, March 6, 1998 @2p

GelTex Participants:

Steven Burke: M.D.	**VP of Clinical Research**
Martha Carter:	**VP Regulatory Affairs**
David Rosenbaum	**Sr. Dir.of PreClinical Research**
Lisa D'Attanasio	**Regulatory Affairs Coordintor**

FDA Participants:

Bruce Schnieder, M.D.	**Reviewing Medical Officer**
Jena Weber, B.S.	**Regulatory Health Project Manager**

Topics for discussion:

1. Non-absorbability of RenaGel (submitted 2/13/98)
2. Predialysis protocol in support of expanding indication to chronic renal failure patients (under IND 46,601).

Absorption - animal studies that were done are excellent, with the use of a triple label; human studies appear adequate also.
Concern - what may be claimed in human (normal volunteers) may not be 100% applicable with those with uremic guts. However, we will accept their proposal(s). Note that studies indicate that RenaGel is not absorbed in uremic rats. Studies also show that the drug was excreted entirely in the feces with no significant absorption. We stated that the labeling will have to reflect this and we will work with the company on fine tuning the labeling as we draw closer to issuing an action letter.

Pre-dialysis - taking place in 4 European sites; final reports should be available around May of 1999. This will form the basis of a supplemental NDA. We discussed the possibility of changing the protocol design to include controls. We plan to meet internally to discuss this issue. We will get back to the GelTex representatives as soon as a decision has been finalized.

Dog absorption study has been completed. Concomitant therapies discussed; maybe 20% of patients enrolled will also be on Digoxin.
Updated safety information/data will be supplied to us.

Jena Weber, RHPM

/S/

Bruce Schneider, M.D.

/S/

APPEARS THIS WAY
ON ORIGINAL

NDA 20-926

DEC - 5 1997

GelTex Pharmaceuticals, Inc.
Attention: Steven K. Burke, M.D.
Nine Fourth Avenue
Waltham, MA 02154

Dear Dr. Burke:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: RenaGel (sevelamer hydrochloride)

Therapeutic Classification: Standard

Date of Application: November 3, 1997

Date of Receipt: November 3, 1997

Our Reference Number: NDA 20-926

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on January 2, 1998, in accordance with 21 CFR 314.101(a).

If you have any questions, please contact Ms. Jena Weber, Regulatory Health Project Manager, at 301-827-6422.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

/S/ 12/5/97

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-926
HFD-510/Div. Files
HFD-510/CSO/JWeber
HFD-510/BSchneider/GTroendle/EBarbehenn/RSteigerwalt/MHaber/DGWu/JMele
ENevius/CJones/AYAhn

DISTRICT OFFICE

Drafted: JWeber 12/4/97/N20926ACK
cc: Egalliers 12/4
Final: Jweber 12/4/97 /S/

ACKNOWLEDGEMENT (AC)

APPEARS THIS WAY
ON ORIGINAL

GelTex
PHARMACEUTICALS, INC.

October 30, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 024
Labeling

Dear Dr. Sobel:

Reference is made to the NDA cited above and to your facsimile dated October 30, 1998. We are pleased to provide a revised draft package insert for Renagel® Capsules which incorporates the changes requested in your facsimile. The changes are noted in strikeout and 18-point font.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

October 20, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 021
Labeling

Dear Dr. Sobel:

Reference is made to the NDA cited above and to your facsimile dated October 20, 1998. We are pleased to provide a revised draft package insert for Renagel® Capsules which incorporates the changes requested in your facsimile. The changes are noted in strikeout and 18-point font.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

October 9, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 020
Labeling

Dear Dr. Sobel:

Reference is made to the NDA cited above and to telephone conversations with Mr. Randy Hedin on October 7, 1998 and October 9, 1998. We are pleased to provide a revised draft package insert, bottle labels and carton labeling for Renagel Capsules which incorporate the changes requested in these conversations. The changes requested by Dr. Houn, as well as the one requested today are noted in strikeout and 18-point font.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex PHARMACEUTICALS, INC.

October 8, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 018
Response to Phase 4 Commitment

Dear Dr. Sobel:

Reference is made to the NDA cited above and to Amendment No. 014 dated October 1, 1998. Reference is also made to a telephone conversation with Mr. Randy Hedin on October 8, 1998. In response to Mr. Hedin's request, we are submitting a revised Phase 4 commitment, as follows:

We hope this response is satisfactory. Should you have any comments or require additional information, please contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter

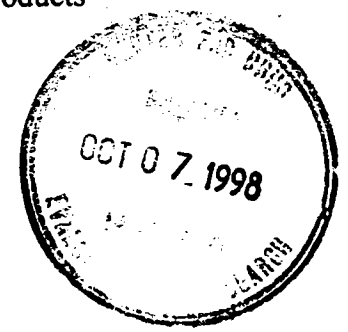
Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

October 5, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857



Re: NDA 20-926 Renagel® Capsules
Amendment Number 015
Safety Update

Dear Dr. Sobel:

Reference is made to the NDA cited above for Renagel® Capsules. The purpose of this submission is to provide the enclosed safety update to NDA 20-926. Please note the four-month safety update was submitted as Amendment No. 005 on March 13, 1998.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

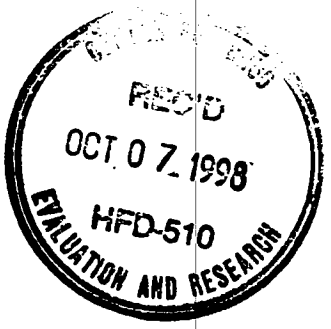
Martha J. Carter.

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

October 5, 1998



Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 016
Labeling

Dear Dr. Sobel:

Reference is made to the NDA cited above and to our videoconference of October 2, 1998. We are pleased to provide a revised package insert for Renagel Capsules which reflects the outcome of our discussions. In particular, we would like to draw your attention to the "Adverse Reactions" section, where we have added the information requested during the conference. We hope this meets with the Division's and the Office's approval. We have used strikeout and 18 point font to highlight changes from the version faxed to us on October 2, 1998.

We would like to offer the following comment about our approach to the "Adverse Reactions" section. While we understand the desire to include the data from the calcium acetate controlled study, this represents only 20% of the entire patient safety database. We feel it is important to include some information from the randomized, double-blind, placebo-controlled study and the long term extension study. Therefore, a paragraph has been included about each study in this section.

Also included in this submission are copies of the bottle and carton labeling, as well as the artwork for the imprint on the capsule which has been changed from "RenaGel" to "G403."

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

Re: NDA 20-926 Renagel® Capsules
Amendment Number 016
Labeling

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

GelTex
PHARMACEUTICALS, INC.

October 1, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

"C"

Re: NDA 20-926 Renagel® Capsules
Amendment Number 014
Response to Phase 4 Commitment

Dear Dr. Sobel:

Reference is made to the NDA cited above and to your facsimile dated September 28, 1998. Reference is also made to a telephone conversation on September 29, 1998 with Dr. Michael Fossler of your Division. In response to your request, we are submitting a Phase 4 commitment, as follows:

We hope this response is satisfactory. Should you have any comments or require additional information, please contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter.

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex PHARMACEUTICALS, INC.

October 1, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 008
Data Sets for Clinical Protocol GTC-36-301
"An Open Label Cross-Over Study of RenaGel™
and Calcium Acetate in Hemodialysis Patients"

Dear Dr. Sobel:

Reference is made to the NDA cited above for Renagel® Capsules. The purpose of this submission is to provide the enclosed information as a formal amendment to NDA 20-926. Please note that this amendment is an exact duplicate of the information sent to Joy Mele, at her request, by Federal Express on September 3, 1998. The information contained includes diskettes and tables. As requested, a desk copy is also being forwarded to Mr. Randy Hedin. BS

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter.

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

September 3, 1998

Joy D. Mele, M.S. (HFD-715)
Food and Drug Administration - CDER
Division of Biometrics 2, HFD-715
Parklawn Building, 10B06
5600 Fishers lane
Rockville, MD 20857-1706

RE: NDA 20-926 Renagel ® (sevelamer hydrochloride) - Dataset for Protocol GTC-36-301

Dear Ms. Mele:

As requested, I am forwarding to you the SAS dataset for Protocol GTC-36-301. Data for Protocols GTC-36-302 and GTC-45-901 are currently being prepared and will be sent to you next week. Enclosed please find the following:

1. 3.5" diskette containing a SAS dataset Version 6.12 formatted for Windows 95.
2. 3.5" diskette containing a SAS transport file. To import the SAS transport file, copy the file onto your network and submit the program included on the diskette called IMPORT.SAS. There are directions at the beginning of the program to define the subdirectory on which you would like the file saved.
3. Documentation outlining the variable names, labels, and formats.
4. PROC CONTENTS output.
5. Printout of 50 observations.

A second copy of these materials are being submitted to HFD-510 to be filed with the application. If you have any questions regarding these data or a need for additional data, please call me at (781) 290-5888 x 760.

Sincerely,

Maureen Dillon

Maureen Dillon, M.A.
Assistant Director, Clinical Research

cc: Martha Carter, V.P. Regulatory Affairs, GelTex Pharmaceuticals, Inc.

0001

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) ~~290-5899~~ 895-4980 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

October 1, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 009
Response to Nonclinical Pharmacology and Toxicology Questions

Dear Dr. Sobel:

Reference is made to the NDA cited above for Renagel® Capsules. The purpose of this submission is to provide the enclosed information as a formal amendment to NDA 20-926. Please note that this amendment is an exact duplicate of the information sent to Randy Hedin by facsimile on September 4, 1998. This information was originally sent in response to FDA questions of August 31, 1998 and is a revision to Sections 5.3 and 5.4 of NDA 20-926 (see volume 010, pages 0049 and 0064, respectively) of the November 3, 1997 submission. As requested, a desk copy is also being forwarded to Mr. Randy Hedin.

BP

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter.

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex PHARMACEUTICALS, INC.

September 4, 1998

Randy Hedin, R.Ph.
Food and Drug Administration
Division of Metabolic and Endocrine Drug Products
HFD-510
5600 Fishers Lane
Rockville, MD 20857

RE: NDA 20-926 RenaGel® Capsules
Responses to Pharmacology Section Questions

Dear Mr. Hedin:

Attached please find responses to the pharmacology section questions sent via facsimile on August 31, 1998.

Please let us know if you would like us to submit these responses as a formal submission to the RenaGel NDA.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter.

Martha J. Carter
Vice President, Regulatory Affairs

0001

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

October 1, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 011
Data Sets for Clinical Protocol GTC-36-302
"An Open Label, Dose Titration Study of Renagel™ in Hemodialysis Patients"

Dear Dr. Sobel:

Reference is made to the NDA cited above for Renagel® Capsules. The purpose of this submission is to provide the enclosed information as a formal amendment to NDA 20-926. Please note that this amendment is an exact duplicate of the information sent to Joy Mele, at her request, by Federal Express on September 9, 1998. The information contains diskettes and tables. As requested, a desk copy is also being forwarded to Mr. Randy Hedin.

BS

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

September 9, 1998

Joy D. Mele, M.S.
Statistical Reviewer
Food and Drug Administration - CDER
17212 Falstaff Lane
Olnely, MD 20832

RE: NDA 20-926 Renagel ® (sevelamer hydrochloride) - Dataset for Protocol GTC-36-302

Dear Ms. Mele:

As requested, I am forwarding to you the SAS dataset for Protocol GTC-36-302. Data for Protocol GTC-45-901 is currently being prepared and will be sent to you later this week. Enclosed please find the following:

1. 3.5" diskette containing a SAS dataset Version 6.12 formatted for Windows 95.
2. 3.5" diskette containing a SAS transport file. To import the SAS transport file, copy the file onto your network and submit the program included on the diskette called IMPORT.SAS. There are directions at the beginning of the program to define the subdirectory on which you would like the file saved.
3. Documentation outlining the variable names, labels, and formats.
4. PROC CONTENTS output.
5. Printout of 50 observations.

A second copy of these materials are being submitted to HFD-510 to be filed with the application. If you have any questions regarding these data or a need for additional data, please call me at (781) 290-5888 x 760.

Sincerely,

Maureen Dillon

Maureen Dillon, M.A.
Assistant Director, Clinical Research

cc: Martha Carter, V.P. Regulatory Affairs, GelTex Pharmaceuticals, Inc.

0001

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

October 1, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 012
Response to Nonclinical Pharmacology and Toxicology Questions

Dear Dr. Sobel:

Reference is made to the NDA cited above for Renagel® Capsules. The purpose of this submission is to provide the enclosed information as a formal amendment to NDA 20-926. Please note that this amendment is an exact duplicate of the information sent to Randy Hedin by facsimile on September 11, 1998. This information was originally sent in response to FDA questions of August 31, 1998, and is a revision to Sections 5.3 and 5.4 of NDA 20-926 (see volume 010, pages 0049 and 0064, respectively). As requested, a desk copy is also being forwarded to Mr. Randy Hedin. BP

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter.

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex PHARMACEUTICALS, INC.

September 11, 1998

Randy Hedin, R.Ph.
Food and Drug Administration
Division of Metabolic and Endocrine Drug Products
HFD-510
5600 Fishers Lane
Rockville, MD 20857

RE: NDA 20-926 RenaGel® Capsules
Responses to Pharmacology Section Questions

Dear Mr. Hedin:

Attached please find the responses to the pharmacology section questions sent via facsimile on August 31, 1998, that were not addressed in our fax of September 4, 1998.

We will also submit these responses as a formal submission to the RenaGel NDA.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Lisa A D'Attanasio
for Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

0001

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex PHARMACEUTICALS, INC.

October 1, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 013
Data Sets for Protocol GTC-45-901
"An Extended Use Study of Renagel in Hemodialysis Patients"

Dear Dr. Sobel:

Reference is made to the NDA cited above for Renagel® Capsules. The purpose of this submission is to provide the enclosed information as a formal amendment to NDA 20-926. Please note that this amendment is an exact duplicate of the information sent Joy Mele, at her request, by Federal Express on September 15, 1998. The information contained includes diskettes and tables. As requested, a desk copy is also being forwarded to Mr. Randy Hedin.

BS

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter.

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

September 15, 1998

Joy D. Mele, M.S.
Statistical Reviewer
Food and Drug Administration - CDER
17212 Falstaff Lane
Olnely, MD 20832

RE: NDA 20-926 Renagel ® (sevelamer hydrochloride) - Dataset for Protocol GTC-45-901

Dear Ms. Mele:

As requested, I am forwarding to you the SAS dataset for Protocol GTC-45-901. Enclosed please find the following:

1. 3.5" diskette containing a SAS dataset Version 6.12 formatted for Windows 95.
2. 3.5" diskette containing a SAS transport file. To import the SAS transport file, copy the file onto your network and submit the program included on the diskette called IMPORT.SAS. There are directions at the beginning of the program to define the subdirectory on which you would like the file saved.
3. Documentation outlining the variable names, labels, and formats.
4. PROC CONTENTS output.
5. Printout of about 50 observations.

A second copy of these materials are being submitted to HFD-510 to be filed with the application. If you have any questions regarding these data or a need for additional data, please call me at (781) 290-5888 x 760.

Sincerely,

Maureen Dillon

Maureen Dillon, M.A.
Assistant Director, Clinical Research

cc: Martha Carter, V.P. Regulatory Affairs, GelTex Pharmaceuticals, Inc.

0001

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex PHARMACEUTICALS, INC.

October 1, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Document Room, 14B-03
HFD-510
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926 Renagel® Capsules
Amendment Number 007
Final Clinical Study Report GTC-45-901
"An Extended Use Study of Renagel in Hemodialysis Patients"

Dear Dr. Sobel:

Reference is made to the NDA cited above for Renagel® Capsules. The purpose of this submission is to provide the enclosed information as a formal amendment to NDA 20-926. Please note that this amendment is an exact duplicate of the information sent to Dr. Bruce Schneider, at his request, by Federal Express on September 2, 1998. The information contained includes a disk and tables. As requested, a desk copy is also being forwarded to Mr. Randy Hedin. BM

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

September 2, 1998

Bruce S. Schneider, M.D.
Medical Officer
Division of Metabolic & Endocrine Drug Products, HFD-510
Room 14B04
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: NDA 20-926
Renagel® Capsules (sevelamer hydrochloride)

Dear Dr. Schneider:

As requested in our telephone conversation yesterday afternoon, we are enclosing the following information pertaining to the extended use study (Protocol No. GTC-45-901):

1. Disk containing the text of the final report. The appendices to this report are available in hard copy and can be submitted, should you wish to see them. Also on this disk are two tables containing an analysis over time of the variables you requested (Vitamins A, D, E; calcium; CO_2; prothrombin time; and chloride), along with a narrative discussing the findings.

2. Hard copies of the ASCII tables that are an appendix to the final report.

We hope this information is responsive to your request. Please contact me at (781) 290-5888, ext. 766, or Lisa D'Attanasio at (781) 290-5888, ext. 716, at any time if we can be of assistance.

Sincerely yours,

Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

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GelTex
PHARMACEUTICALS, INC.

September 8, 1998

Randy Hedin, R.Ph.
Food and Drug Administration
Division of Metabolic and Endocrine Drug Products
HFD-510
5600 Fishers Lane
Rockville, MD 20857

RE: NDA 20-926 RenaGel® Capsules
Responses to Biopharmaceutics Section Questions

Dear Mr. Hedin:

Attached please find responses to the biopharmaceutics section questions sent via facsimile on August 31, 1998. We have referred your questions (Attachment 1) concerning the analytical portion of Study GTC-10-801 to [redacted] Scientist at [redacted] where the study was conducted on behalf of GelTex. We have attached [redacted] responses to your questions (Attachment 2). We also have attached the data requested in question 3 (Attachment 3).

Dr. Schneider in a recent teleconference asked if [redacted] saved fecal, blood, or urine specimens from the study. We have been informed that [redacted] did not save specimens.

Please call if you need clarification or additional information. If necessary, we can arrange a conference call [redacted]

Please let us know if you would like us to submit these responses as a formal submission to the RenaGel NDA.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator at extension 716.

Sincerely,

Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

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Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

GelTex
PHARMACEUTICALS, INC.

September 30, 1998

Solomon Sobel, M.D.
Director, Division of Metabolic and Endocrine Drug Products
Division Document Room, 14B-03
HFD-510
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: NDA 20-926, Renagel® Capsules
Response to Labeling Comments

Dear Dr. Sobel:

Reference is made to the NDA cited above and to your facsimile dated September 29, 1998. The purpose of this letter is to respond to your comments on the draft package insert for Renagel® Capsules. We would like to thank you for the care and interest that have been taken in reviewing the labeling. We found the comments to be useful and constructive. A draft insert is attached with changes from your version noted with boldface type or strikeouts. In addition, we would like to offer the following comments.

Nine Fourth Avenue Waltham, MA 02451 Phone: (781) 290-5888 Fax: (781) 290-5890 Website: www.geltex.com

We appreciate your efforts in reviewing our NDA and look forward to a successful conclusion to our labeling discussion on October 2nd. In the meantime, should you have further comments, please contact Martha J. Carter at (781) 290-5888, extension 766 or Lisa D'Attanasio, Regulatory Affairs Coordinator, at extension 716.

Sincerely,

Martha J. Carter.

Martha J. Carter,
Vice President Regulatory Affairs

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GelTex PHARMACEUTICALS, INC.

September 2, 1998

Bruce S. Schneider, M.D.
Medical Officer
Division of Metabolic & Endocrine Drug Products, HFD-510
Room 14B04
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NEW CORRESP

RE: NDA 20-926
Renagel® Capsules (sevelamer hydrochloride)

/S/

Dear Dr. Schneider:

As requested in our telephone conversation yesterday afternoon, we are enclosing the following information pertaining to the extended use study (Protocol No. GTC-45-901):

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Sincerely yours,

Martha J. Carter

Martha J. Carter
Vice President, Regulatory Affairs

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

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