

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020926

CHEMISTRY REVIEW(S)

OCT - 7 1998

Hedin

DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-926 **DATE REVIEWED:** October 6, 1998

CHEMISTRY REVIEW #: 1 **REVIEWER:** Martin Haber, Ph.D.

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	11/3/97	11/3/97	11/10/97
AMENDMENT	1/21/98	1/22/98	
AMENDMENT	8/4/98	8/5/98	

NAME & ADDRESS OF SPONSOR: Gel Tex Pharmaceuticals, Inc.
Nine Fourth Ave.
Waltham, MA 02154 (781) 290-5888

DRUG PRODUCT NAME:
Proprietary: RenaGel
Nonproprietary: Allylamine polymer with 1-chloro-2,3-epoxypropane, hydrochloride (IUPAC)
Sevelamer HCl (USAN)
Code #: GT 16-026A, PB-94
Chem. Type/Therapeutic Class: Type 1, NME/ Class S

PHARMACOL. CATEGORY/INDICATION: Treatment of hyperphosphatemia in patients with renal failure

DOSAGE FORM: Capsules

STRENGTHS: 403 mg

ROUTE OF ADMINISTRATION: Oral

Rx/OTC: X Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA (see next page),

MOLECULAR FORMULA, MOLECULAR WEIGHT:

Poly(allylamine-co-N,N'-diallyl-1,3-diamino-2-hydroxypropane), hydrochloride; 2-Propen-1-amine, polymer with (chloromethyl)oxirane, hydrochloride; Oxirane, (chloromethyl)-, polymer with 2-propen-1-amine, hydrochloride

CAS #: 182683-00-7; approximate formula: (C₃ H₇ N_n·nHCl)_{812z} (C₉ H₁₈ N₂ O_n·nHCl)_{94z} where z is a large number. Because the molecule is a crosslinked polymer.

REMARKS:

Patients with end stage renal failure develop hyperphosphatemia. Existing therapy is a special diet supplemented by calcium or aluminum salts.

The 1/21/98 amendment provides for removal of one the drug substance suppliers. The 8/4/98 amendment provides for changes made to the drug product test methods and specifications as a result of comments from the pre-approval inspection.

CONCLUSIONS & RECOMMENDATIONS:

From a chemistry viewpoint the application is approvable.

Orig. NDA # 20-926
cc: HFD-510/Division file/J.Gibbs/S.Koepke/D-G.Wu/M.Haber/Hedin
ONDC/ODEII

R/D Init. by: Dr. D-G. Wu, Team Leader Chemist

151 10/8/98

1/5/98
Martin Haber, Ph.D.
Review Chemist

Consult #420
935

REQUEST FOR TRADEMARK REVIEW

To: Labeling and Nomenclature Committee
Attention: Dan Boring, Chair, HFD-530, 9201 Corporate Blvd, Room N461

From: Division of Metabolic and Endocrine Drug Products/ HFD-510
Attention: Martin Haber Phone: (301) 443-3520

Date: January 13, 1998

Subject: Request for Assessment of a Trademark for a Proposed Drug Product

Proposed Trademark: RenaGel **NDA #:** 20-926

Company Name: GelTex Pharmaceuticals, Inc.

Established name, including dosage form: Sevelamer hydrochloride capsules

Dosage form: 403 mg capsule

Other trademarks by the same firm for companion products: CholestaGel (proposed)

Indications for Use (may be a summary if proposed statement is lengthy):

Control of Hyperphosphatemia in patients with end stage renal failure

Initial comments from the submitter (concerns, observations, etc.):

The product is an insoluble allylamine polymer crosslinked with 1-chloro-2,3-epoxypropane in the hydrochloride form. It is used to absorb dietary phosphate in patients with renal failure.

filename: 20926trd.mrk

NOTE: *Meetings of the Committee are scheduled for the 4th Tuesday of the month. Please submit this form at least one week ahead of the meeting. Responses will be as timely as possible.*

Rev Dec. 1995

CONSULT #935

LNC TRADEMARK REVIEW

TO: HFD-510

ATTN: Martin Haber

PROPOSED NAME(S): RenaGel

ESTABLISHED NAME: sevelamer hydrochloride capsules

COMMITTEE'S COMMENTS:

A review no names which sound like or look likes the proposed name.

However, the Committee does have a concern about the use of "Gel" in the name. Since gel is an officially recognized dosage in USP, its use in the name of an oral capsule may be misleading.

Other than the concern stated, the Committee has no reason to find the proposed name unacceptable.

 /S/ 3/1/98
Dan Boring, Ph.D., Chairman
Labeling and Nomenclature Committee

APPEARS THIS WAY
ON ORIGINAL

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