

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-637/S-016

Correspondence



February 14, 2003

VIA FAX

Mr. Paul Zimmerman
Project Manager
Division of Oncologic Drug Products (HFD-150)
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20852

RE: NDA 20-637
GLIADEL[®] Wafer (polifeprosan 20 with carmustine implant)
GENERAL CORRESPONDENCE

Dear Mr. Zimmerman:

Reference is made to NDA 20-637 for GLIADEL[®] Wafer (polifeprosan 20 with carmustine implant), Guilford's sNDA submitted April 6, 2001, sNDA amendment, submitted October 25, 2002, and the Agency's fax of today, February 14, 2003.

We have reviewed your fax of February 14, 2003 and we agree with all of the revisions noted. A revised product insert reflecting the revisions as noted in your fax will be formally submitted on Monday, February 17, 2003.

Should you have any comments or questions, please contact me at (410) 631-6356.

Sincerely yours,

A handwritten signature in cursive script that reads "Louise Peltier".

Louise M. Peltier
Senior Director, Regulatory Affairs

LP/kb

GUILFORD PHARMACEUTICALS

Ross S. Laderman
Vice President, Regulatory Affairs

April 5, 1996

VIA FEDERAL EXPRESS

Mr. Paul Zimmerman
Consumer Safety Officer
Division of Oncologic Drug Products (HFD-150)
Attn: Third Floor Document Room
Center for Drug Evaluation & Research
Food and Drug Administration
1451 Rockville Pike
Rockville, Maryland 20852



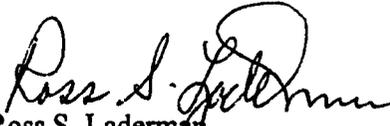
**RE: NDA 20-637, GLIADEL® Wafer (polifeprosan 20 with carmustine)
Amendment - Patent Information**

Dear Mr. Zimmerman:

In response to your request, we have enclosed a copy of patents 5,179,189 and 4,789,724 which are relative to GLIADEL®. This information was faxed to Dr. Donald Klein on April 4, 1996.

If you have any questions, please feel free to contact Louise Peltier at (410)631-6356 or myself.

Sincerely yours,


Ross S. Laderman
Vice President,
Regulatory Affairs

Enclosures

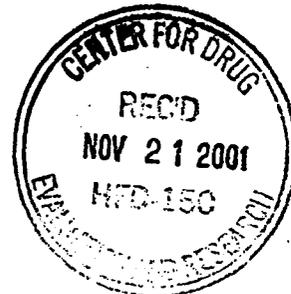
(Submission #010)

GUILFORD PHARMACEUTICALS

November 19, 2001

VIA FAX AND FEDEX

Ms. Linda Carter
Center for Drug Evaluation and Research, HFD-101
Food and Drug Administration
Woodmont, Room 6014
5600 Fishers Lane
Rockville, MD 20857



Dear Ms. Carter:

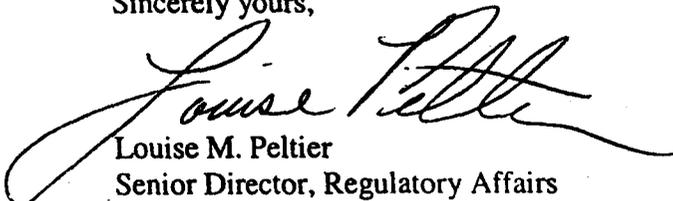
This letter is to update you on Guilford's efforts to collect financial disclosure information from the clinical investigators who participated in the GLIADEL study RPR132596/T-301, Entitled: A Phase III, Multicenter Randomized Double-Blind, Placebo-Controlled Trial of Polifeprosan 20 With Carmustine 3.85% Implant in Patients Undergoing Initial Surgery for Newly Diagnosed Malignant Glioma, which was submitted to our NDA 20-637 on April 6, 2001, Supplement S-016.

On September 20, 2001, the first letter was sent to the 38 principal investigators. Of those 38 FedEx mailings, four were undeliverable. Attempts to obtain current addresses for the four principal investigators have been unsuccessful.

To date, of the two FedEx mailings (made on September 20, 2001 and November 9, 2001), we have received 25 responses, of which six "did" and nineteen "did not" indicate participation in financial arrangements or held financial interests that are require to be disclosed. A total of 14 who received the second letter have not responded.

If you are in need of any additional information and/or have any questions please do not hesitate to contact me at (410) 631-6356.

Sincerely yours,


Louise M. Peltier
Senior Director, Regulatory Affairs

LP/ikb

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

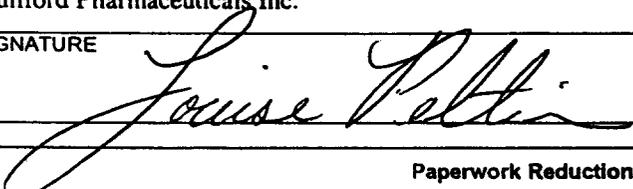
With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Louise Peltier	Senior Director, Regulatory Affairs
FIRM/ORGANIZATION	
Guilford Pharmaceuticals Inc.	
SIGNATURE	DATE
	April 6, 2001

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

Attachment to CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS
OF CLINICAL INVESTIGATORS

The sponsor of this clinical study (T-301), performed to support this sNDA filing, was _____ and was conducted under their IND _____ was responsible for all financial arrangements with all investigators who participated in this study.

Guilford Pharmaceuticals Inc. reacquired the rights to GLIADEL®, including _____ IND and NDA on October 24, 2000. It has not been possible to date to obtain the financial information required to complete item 2 of this Certificate. Guilford has and will continue to make every effort to obtain this information from _____

APPEARS THIS WAY
ON ORIGINAL