DCD/DCB

Quincy Research Center

A Division of BioDesign Institute for Clinical Pharmacology, Inc.
A Member of the Clinical Research Foundation Group

December 12, 1990

Pat Vacherlon
Licensing Section
Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Docket No. 03017692
License No. 24-20055-01

Dear Ms. Vacherlon:

The purpose of this letter is two-fold:

1. To respond to an inspection report (Notice dated Oct 23 1990)

2. To respond to the decommissioning funding plan (Letter dated Nov 2 1990)

In both cases, it is necessary to amend our license to cover three points:

1. Attachment I - change of ownership

2. Attachment II - area survey procedures

3. Attachment III - revision of possession limits, thereby exempting us from decommissioning requirements

We are enclosing a check in the amount of $340.00 to cover the amendment fee for a 7c license. If anything further is required, please let me know. You may reach me at (816) 483-1850.

Sincerely,

Sue Strickler

Sue Strickler
Director, Research Administrative Services

sws

4 encls.

cc: Evelyn Matson

IE07

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ATTACHMENT I

TRANSFER OF OWNERSHIP

Response to Item 2 in NRC Information Notice No. 89-25:

The name of the organization has not changed: Pharmacology Research Corporation (DBA Quincy Research Center).

Personnel listed in the license have not changed: Dr. Dukestein and Dr. Gallagher.

The previous owner of Quincy Research Center, John D. Arnold, M.D., has remained with the Company in a consulting capacity.

Pharmacology Research Corporation (DBA Quincy Research Center) is a wholly-owned subsidiary of Biodesign Institute For Clinical Pharmacology, Inc. On March 10, 1987, Biodesign Institute For Clinical Pharmacology, Inc. acquired all of the outstanding stock of Pharmacology Research Corporation.

At the time of the sale in March, 1987, Mr. James M. Clifford joined Quincy Research Center as President. Upon Mr. Clifford's retirement in August, 1990, John R. Plachetka, Pharm.D., was appointed President/CEO of Quincy Research Center.

No changes have been made in the use, possession or storage of licensed materials.

There have been no changes in record keeping procedures. Records have been available for inspection at all times.

No contamination was present at the time of the sale - No liability was transferred to Biodesign. Our license is being amended to exempt Quincy Research Center from decommissioning requirements.

Biodesign acquired all outstanding stock and assumed all liabilities of Quincy Research Center.

Quincy Research Center commits to abide by all NRC regulations and constraints, conditions, requirements, representations and commitments of our radioactive materials license.

John R. Plachetka, Pharm.D.
President/CEO
Quincy Research Center

ATTACHMENT II

AREA SURVEYS PROCEDURES

We acknowledge that we have not fully complied with area survey procedures.

We iterate our intention to comply with area survey and wipe test requirements in the following manner:

1. Specifically for gamma emitters, we will comply with the model procedure for Area Surveys, Appendix of Regulatory Guide 10.8, Rev. 2

2. For low-energy beta emitters (e.g., C-14 and H-3), we restate our determination to comply with these procedures:

   Wipe sampling will be performed when 14-Carbon and 3-H compounds are used which might lead to surface contamination. All wipe samples obtained for 14-Carbon and 3-H contamination in conjunction with a particular study will be returned to the study sponsor for evaluation. A report of the sponsor's findings will be maintained for inspection by the NRC. It is not anticipated that surveys of any type will be performed when investigational studies with radioactive materials are not being performed.

ATTACHMENT III

REVISION IN LICENSE POSSESSION LIMITS

We wish to modify our license to include only those radioactive materials we are likely to use in medical research, thereby exempting us from decommissioning requirements. Listed below are the revisions:

Element and Mass Number:	Any by-product material with atomic numbers between 1-83 and half-life less than 120 days; H-3; and C-14
Chemical and/or Physical Form:	Any
Maximum Number of millicuries of each form:	20 mCi per isotope for total not to exceed 50 mCi
Describe Purpose of Use:	Pharmacokinetic research in humans. All compounds to be tested will be covered either by "Notice of Claimed Investigational Exemption for a New Drug (IND)" or approval by RDRC No. 68.

PHARMACOLOGY RESEARCH CORPORATION
A DIVISION OF BIODESIGN INSTITUTE FOR CLINICAL PHARMACOLOGY, INC.
A MEMBER OF THE CLINICAL RESEARCH FOUNDATION GROUP
QUINCY RESEARCH CENTER 5100 E. 24TH
KANSAS CITY, MO 64127

Mercantile Bank of Kansas City
Kansas City, Missouri 64106

MERCANTILE BANK

3475

18-18/1010

PAY ----------THREE HUNDRED AND FORTY- AND 00/100---------- DOLLARS

TO THE ORDER OF NUCLEAR REGULATORY COMMISSION

DATE 12/12/90

AMOUNT $340.00

TWO SIGNATURES REQUIRED
VOID AFTER 90 DAYS

Sharon Turpin

Nancy Bell

⑈003475⑈ ⑆101000187⑆ 500 003138⑈

PHARMACOLOGY RESEARCH CORPORATION

DATE	DESCRIPTION	AMOUNT	DISTRIBUTIONS	
			ACCOUNT NO.	AMOUNT
/12/90	AMENDMENT FEE FOR 7C LICENSE	340.00		
	DLT			