NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 02

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

3020 29

Licensee	
1. GFI Pharmaceutical Services, Inc. 2. 800 St. Mary's Drive Evansville, IN 47714	In accordance with letter dated November 4, 1996 3. License Number 13-26640-01 is amended in its entirety to read as follows: 4. Expiration Date August 31, 2005 5. Docket or Reference No. 030-33820

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Iodine-125	A. Pre-packaged kits	A. 500 microcuries
B. Any byproduct material identified in 10 CFR 35.100	B. Any radiopharmaceutical identified in 10 CFR 35.100	B. As needed

9. Authorized Use:

A. To be used for in-vitro studies.

B. Medical use described in 10 CFR 35.100 limited to carbon-14 and hydrogen-3 human research studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at GFI Pharmaceutical Service, Inc., (The Manor), 3rd floor clinic and 4th floor, 800 St Mary's Drive, Evansville, Indiana.

11. A. Licensed material listed in Subitem A. shall be used by, or under the supervision of, Debra Adamson, M.S., Philip Downing, Glacye Splittorff, or Mary Westrick, Ph.D.

9 1 ML 2 30 SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-26640-01

Docket or Reference Number
030-33820

Amendment No. 02

B. Licensed material shall be used by, or under the supervision of, Mark W. Graves, M.D.

12. The Radiation Safety Officer for this license is Philip Downing.

13. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

14. Notwithstanding the requirements of 10 CFR 35.22, the licensee is not required to establish a Radiation Safety Committee.

15. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

16. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35.

17. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-26640-01

Docket or Reference Number
030-33820

Amendment No. 02

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated March 14, 1995; and

B. Letter dated September 6, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 29, 1997

By Patricia J. Pelke
Nuclear Materials Licensing Branch, Region III

JAN 3 0 1997

Philip Downing
Radiation Safety Officer
GFI Pharmaceutical Services, Inc.
800 St. Mary's Drive
Evansville, IN 47714

Dear Mr. Downing:

Enclosed is Amendment No. 02 to your NRC Material License No. 13-26640-01 in accordance with your request.

Please note that we have amended Item 4 (Expiration Date) of your license to include a one-time, five year extension granted to certain licensees published in the Federal Register (61 FR 1109, January 16, 1996).

In addition, Conditions 16. and 17. have been added to your license. Please review these conditions and contact me if you have any further questions.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Sincerely,

Original Signed By
Patricia J. Pelke
Nuclear Materials Licensing Branch

License No.: 13-26640-01
Docket No.: 030-33820

Enclosure: Amendment No. 02

DOCUMENT NAME: M:\03033820.CL7
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII											
NAME	PJPELKE:jaw											
DATE	01/29/97											

OFFICIAL RECORD COPY

302029

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

November 12, 1996

Philip Downing
Radiation Safety Officer
GFI Pharmaceutical Service, Inc.
800 St. Mary's Drive
Evansville, IN 47714

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 11/04/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License X Amendment ___ Renewal

Administrative deficiencies were identified during this initial review as outlined below. However, it should be noted that a technical review may identify additional omissions in the submitted information.

It appears that your request is routine (see 1-3 below as, applicable).

Incomplete information is as follows: An amendment, with the required fee is necessary for us to complete your request to change radiation safety officers. Please contact our License Fee & Debt Collection Branch, located in our headquarters office, as referenced below, to obtain the correct fee amount.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however under timely filing (before expiration) you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302029
License No. 13-26640-01

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02410
Status Code: 0
Fee Category: 3P
Exp. Date: 20050831
Fee Comments:
Decom Fin Assur Reqd: N

R4

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: GFI PHARMACEUTICAL SERVICE, INC.
   Received Date: 961107
   Docket No: 3033820
   Control No.: 302029
   License No.: 13-26640-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: ~~---~~ 0
   Check No.: ~~---~~

3. COMMENTS

Signed D. Hersey
Date 11-25-96

1996 NOV 12 PM 2:17

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ( ))

1. Fee Category and Amount: 3P $300

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 12/5/96

Log NOV 7 III
Remitter
Check No. 36110
Amount $300
Fee Category 3P
Type of Fee AmD
Date Check Rec'd 12/5/96
Date Completed
By: SC

DEC 09 1996

PHARMACEUTICAL
SERVICES, INC.

November 4, 1996

Patricia J. Pelke
Nuclear Materials Licensing Section
Nuclear Regulatory Commission, Region III
801 Warren Road
Lisle, IL 60532-4351

Dear Ms. Pelke:

GFI Pharmaceutical Services, Inc. hereby requests amendment of License Number 13-26640-01 as follows. Please change the Radiation Safety Officer, Item 12, to Philip Downing. Also add Mr. Downing to Item 11 as an authorized user. Attached is a completed Supplement A plus a copy of Mr. Downing's resume. Mr. Downing has worked under my supervision as well as under Ms. Splittorff's for the past three years and has just completed a 40 hour training course entitled "Radiation Safety Officer" from CSI. Also, under Item 11A, please delete my name from the list of authorized users. Finally, under Item 8A, please increase the maximum possession amount of ^{125}I to 500 μCi as we will be switching to a new TSH RIA kit containing an increased amount of ^{125}I.

I feel Mr. Downing is well qualified to assume my duties when I retire next month. Please do not hesitate to contact me or Mr. Downing at 812/474-6530. It has been a pleasure working with you.

Sincerely,

Methodius J. Bartek

Methodius J. Bartek, Ph.D.
Radiation Safety Officer

MJB/rlv

Attachments

cc: Philip Downing, B.A.
Debra Adamson, M.S.
Greg Folz, B.S.
Glacye Splittorff, BS MT(ASCP)
Mary Westrick, Ph.D.

RECEIVED
NOV 07 1996
REGION III

NOV 07 1996

Pm: 11-4-96

800 St. Mary's Drive • Evansville, Indiana 47714 • 812-474-6530 • FAX 812-474-6539

302029

SUPPLEMENT U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Philip A. Downing, B.A.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY	TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	"Basics of Liquid Scint. Counting", Canberra Ind. Meriden, CT 1994	16 hrs.	
b. RADIATION PROTECTION	"Radiation Safety Officer" CSI-Radiation Safety Training Bethesda, MD 1996	40 hrs.	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Items in C and D were covered in the above training course.		
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
^{14}C	$\leq$ 15 m Ci	GFI Pharmaceutical Serv. Evansville, IN 1994 - Present	$\geq$ 800 hours	Liquid Scint. Counting/Oxid.
^{125}I	$\leq$ 0.035 m Ci	GFI Pharmaceutical Serv. Evansville, IN 1994 - Present	$\geq$ 1000 hours	RIA Procedures.
^{57}Co	$\leq$ 0.020 m Ci	GFI Pharmaceutical Serv. Evansville, IN 1994 - Present	$\geq$ 200 hours	RIA Procedures

CURRICULUM VITAE

OF

Philip A. Downing

ADDRESS 6411 Phillips Road, Box 67
Tennyson, Indiana 47637
812-567-4222

DATE OF BIRTH December 12, 1969

EDUCATION Indiana University, Bloomington, Indiana

1988-1993	B.A. in Chemistry
1988-1993	B.A. in Biology

CONTINUING EDUCATION

1996	CSI - Radiation Safety Training, Bethesda, Maryland "Radiation Safety Officer" - 40 hours
1995	Chromatography Institute of America, Medfield, Massachusetts "Normal and Reverse Phase HPLC"
1994	Canberra Industries, Inc., Meriden, Connecticut "LS-101-2 "Basics of Liquid Scintillation Counting"

ORGANIZATIONS

1996-Present	Association of Official Analytical Chemists (AOAC)
1994-Present	American Chemical Society (ACS)
1993-Present	Scottish Rite, Evansville, Indiana
1991-Present	Alfa Chi Sigma - Professional Chemistry Fraternity
1991-Present	Masonic Lodge, Gentryville, Indiana

AWARDS

1988	National Youth Leadership Award Congressional Youth Leadership Council, Washington, D.C

CURRENT PROFESSIONAL APPOINTMENTS

1996 - Present	Radiation Safety Officer GFI Pharmaceutical Services, Inc. Evansville, Indiana
1996 - Present	Analytical Scientist GFI Pharmaceutical Services, Inc. Evansville, Indiana

Duties/Testing performed:

High performance liquid chromatography (HPLC)
Liquid Scintillation analyzing - oxidizing and counting
Radioimmunoassay
Toxicology (TLC)
Special analytical procedures
Clinical Drug Preparation
Various Clinical laboratory testing
Complete test validations
Write testing procedures

1994 - 1996 Laboratory Technician
GFI Pharmaceutical Services, Inc.
Evansville, Indiana

Analytical Validations

1. Validation of a Radioimmunoassay for C-Peptide in Human Serum, V022.2: January 17, 1995.

2. Validation of a Radioimmunoassay for the Determination of Renin Activity in Human Plasma - Clinical Assays, V025.2: July 20, 1995.

3. Validation of a High Performance Liquid Chromatographic Assay for Nicotine and Cotinine in Urine, V026.2: September 9, 1995.

4. Validation of the Radioimmunoassay procedure for Luteinizing Hormone and Follicle Stimulating Hormone in Human Serum, V020.2: October 10, 1995.

5. Validation of High Performance Liquid Chromatographic Assay for NELFINAVIR MESYLATE (AG1343) in Plasma, V030.2: June 20, 1996.

In-House Reports

1. Urine Digoxin Levels, Wyeth-Ayerst Research, Study #820-A-119-US, GFI Study #WA95-378, September 9, 1995.

2. Freeze-Thaw Stability of Digoxin in Urine, Wyeth-Ayerst Research, Study #820-A-119-US, GFI Study #WA95-378, September 18, 1995.

3. Serum Aldosterone Levels, Wyeth-Ayerst Research, Study #820-A-131-US, GFI Study #WA95-385, September 18, 1995.

4. Serum Aldosterone Levels, Wyeth-Ayerst Research, Study #820-A-120-US, GFI Study #WA95-385, September 23, 1995.

5. Serum Aldosterone Levels, Wyeth-Ayerst Research, Study #820-A-119-US, GFI Study #WA95-385, October 02, 1995.

6. Serum Aldosterone Levels, Wyeth- yerst Research, Study #820-A1-135-US, GFI Study #WA95-385, March 5, 1996.

7. Long Term Stability of Digoxin in Urine at < -20°C, Wyeth-Ayerst Research, Study #820-A-119-US, GFI Study #WA95-378, June 11, 1996.

8. Serum Aldosterone Levels, Wyeth-Ayerst Research, Study #820-A1-135-US, GFI Study #WA95 - 385, August 30, 1996

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

GFI PHARMACEUTICAL SERVICES, INC.
ATTN: METHODIUS J. PARTEK, PH.D.
RADIATIONSAFETY OFFICER
800 ST. MARY'S DRIVE
EVANSVILLE, INDIANA 47714

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 11-4-96

LICENSE NUMBER: 13-16640-01

CONTROL NUMBER: 302029

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3P	$	$	$ 300.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 300.00
PAYMENT RECEIVED	$ 0.00
AMOUNT DUE	$ 300.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of $ _____. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.

☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	LFDCB	LFDCB
Shirley Crutchfield SC		
SHIRLEY CRUTCHFIELD	11/15/96	

Distribution: OC/DAF/RF
Pending Fee File: OC/DAF/SF(LF-3.2.7)
LFARB R/F (2) Region 3

DATE: Nov. 15, 1996

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.