

RECEIVED

DNMS

18 September 2012

Regional Administrator U.S. Nuclear Regulatory Commission, Region IV **Division of Nuclear Materials Safety** Licensing Assistant Section 1600 East Lamar Blvd Arlington, TX 76011-4511

SUBJECT:

Amendment NRC Lic: 49-27629-01MD

PharmaLogic respectfully requests the following amendment to the commercial nuclear pharmacy US NRC Radioactive Materials License # 49-27629-01MD. The facility is located at 3480 Trigood Drive, Suite 2, Casper, Wyoming 82609.

Add James Cordonier, PharmD as an Authorized Nuclear Pharmacist. This individual has completed the Purdue University Pharmacy Certificate Program and required supervised practical experience. The course completion letter, program certificate, synopsis of course clock hours, NRC Form 313A(ANP) and Pharmacist License documentation are attached.

I wish to thank you for your consideration of this request. If there are any further questions, please contact me.

Sincerely,

Gerard A. Strugala, RPh, BCNP Vice President, Operations

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☐ Immediate Release

Normal Release

NON-PUBLIC

☐ A.3 Sensitive-Security Related

☐ A.7 Sensitive Internal

Other:

TC Date: 9-19-12

PharmaLogic Holdings 1 S. Ocean Boulevard + Suite 206 + Boca Raton + Florida 33432 732-539-9395 • 561-416-0083 FAX



COLLEGE OF PHARMACY

August 29, 2012

James H. Cordonier II Pharmalogic WY Inc. 3840 Inguish Drive Casper, MY 82609

Dear James,

We are pleased to provide the enclosed certificate to recognize formally your completion of the Purdue University Nuclear Pharmacy Certificate Program. You have successfully completed all requirements of both the distance and oncampus components of the program as set forth by the Nuclear Regulatory Commission and Purchie University. We enjoyed the brief opportunity to share our knowledge from the world of academia. We wish you the very best for a gratifying and successful professional career.

As you continue on in your career, please do not hesitate to let us know if we can be of any assistance to you - we consider you part of the "Purdue family" and we look forward to hearing from you in the future!

Sancerely,

Jana D. W. collecenon

Kara Duncan Weatherman, PharmD, BCNP, FAPhA Clinical Assistant Professor of Pharmacy Practice Unclear Pharmacy Programs Pareline University

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PURDUE UNIVERSITY

memo

TO:

James H. Cordonier II

FROM:

Kara Duncan Weatherman, PharmD, BCNP, FAPhA

DATE:

August 29, 2012

SUBJECT: Nuclear Pharmacy Certificate Program Completion

James -

Congratulations on completing the Purdue University Nuclear Pharmacy Certificate Program! Enclosed are a number of documents that will be necessary as you apply for Authorized Nuclear Pharmacist status:

- COMPLETION LETTER: this is an official letter (on Purdue letterhead) stating that you have successfully completed the training program and met all of the requirements that have been set forth by both the Nuclear Regulatory Commission and Purdue University. I generally send two original copies - one for submission and one for your records.
- FINAL CERTIFICATE: a copy of this can also be included in your request for AU status and if you so desire, can be framed for your personal use.
- SYNOPSIS OF CLOCK HOURS: this document summarizes the hourly breakdown of your training in the categories specified by the U.S. Nuclear Regulatory Commission. Please note, page 5 of the document, entitled "Training Received in Basic Radioisotope Handling Techniques", summarizes the total breakdown of course content for both the distance and campus sessions in chart form. This document contains my signature as Director of Nuclear Pharmacy Training Programs.

Keep in mind, Purdue certifies your 200 hours of didactic training only - you will need to have an Authorized Nuclear Pharmacist from your facility (or from previous training experiences if you are counting hours earned during a summer internship or other experience) submit an affidavit indicating 500 hours of practical experience. Please let me know if we can be of any additional assistance in this process. It is usually helpful if you make copies of all of the documents and keep them in your personal files in case you change jobs and need to resubmit your AU status to a different state. I also keep electronic files of all paperwork associated with the program. Just give us a call if you ever need them.

In conclusion, I would like to wish you the best as you embark on this new phase of your career. Nuclear pharmacy is a fantastic area of practice, and hopefully, you will find that you enjoy it as much as I have in my career. I would encourage you to continue your education in nuclear medicine and nuclear pharmacy. An excellent method is to become active in your local nuclear medicine technology organization or to become a member of the American Pharmacist Association's section on nuclear pharmacy. Purdue's Certificate Program has given you a foundation that you can build on, and our faculty remains available to you if you have questions at a later date. Please do not hesitate to contact us if we can be of ANY help.

Enclosures

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

James II. Cordonier II Certificate Program #77 Campus session: August 2012

College of Pharmacy

Department of Pharmacy Practice

Nuclear Pharmacy Programs

Purdue University

West Lafayette, Indiana 47907

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PURDUE UNIVERSITY

WEST LAFAYETTE INDIANA

COLLEGE OF PHARMACY DEPARTMENT OF PHARMACY PRACTICE NUCLEAR PHARMACY PROGRAMS

THIS CERTIFICATE IS AWARDED TO

James H. Cordonier II

AS IVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

August 29, 2012

Jose D. Weathcomer



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General affrigate_

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☐ Immediate Release

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☐ A.3 Sensitive-Security Related

☐ A.7 Sensitive Internal

Other:

TC Date: 9-19-12

PharmaLogic Holdings 1 S. Ocean Boulevard • Suite 206 • Boca Raton • Florida 33432 732-539-9395 * 561-416-0083 FAX



COLLEGE OF PHARMACY

August 29, 2012

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Sincerely,

Your D. W.colkerman

Vara Duncan Weatherman, PharmD, BCNP, FAPhA Clinical Assistant Professor of Pharmacy Practice Unclear Pharmacy Programs Purche University

1. Sankar Pharmas y Programs Department of Pharmacy Practice

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PURDUE UNIVERSITY

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TO:

James H. Cordonier II

FROM:

Kara Duncan Weatherman, PharmD, BCNP, FAPhA

DATE:

August 29, 2012

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- FINAL CERTIFICATE: a copy of this can also be included in your request for AU status and if you so desire, can be framed for your personal use.
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Enclosures

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

James II. Cordonier II Certificate Program #77 Campus session: August 2012

College of Pharmacy
Department of Pharmacy Practice
Nuclear Pharmacy Programs
Purdue University
West Lafayette, Indiana 47907

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PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

COLLEGE OF PHARMACY
DEPARTMENT OF PHARMACY PRACTICE
NUCLEAR PHARMACY PROGRAMS

THIS CERTIFICATE IS AWARDED TO

James H. Cordonier II

AS EVIDENCE OF COMPLETION OF THE

NUCLEAR PHARMACY CERTIFICATE PROGRAM

August 29, 2012

Jana D. Weatherman

Form Updated 08/11

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES®

Trainee: James H. Cordonier II Date issued: 08/29/2012

			Breakdown of Course Content in Clock Hours					
Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Radiation Physics & Instru- mentation	Radiation Protection	Math Pertaining to Radio- activity	Radiation Biology	Radio- pharma- ceutical Chemistry
Purdue University	July 2012 - August 2012	DVD- Workbook	150	51	33	13	21	32
	August 2012	On-Site	65	34	13	10	o	8
	Total Hours Re	eceived	215					
Hourly breakdown by topic			85	46	23	21	40	

^{*} This form is representative of that which is used to apply for an NRC license amendment for an authorized user.

Director of Nuclear Pharmacy Training Programs:

Kara Duncan Weatherman, PharmD, BCNP, FAPhA Clinical Assistant Professor of Pharmacy Practice

Purdue University

Nuclear Pharmacy Programs

Nuclear Pharmacy Certificate Program DVD and Workbook (Self-Study Portion) Clock Hours

DVD	Instructor	Hours
Physics and Overview	Dr. Stanley M. Shaw	RP/I: 11
Disc 1-4	1	RP: 4
		MA: Γ
Radiation Protection Disc 1-2	Dr. Paul Ziemer	RP. 8
Instrumentation Disc 1	Dr. Kara Weatherman	RP/I: 4
Radiopharmaceuticals	Dr. Kara Weatherman	RP: 3
Disc 1-3		RB: 3
		RC: 6
Math Review Disc 1	Dr. Kara Weatherman	MA: 4
Radionuclide Generators	Ms. C. Anne Smith	RP.1: 2
Disc I		MA: 2
Kit Preparation Disc 1	Dr. Kara Weatherman	MA: 4
Quality Control	Ms. C. Anne Smith	RP/I: 2
Disc 1		MA: 1
		RC: 1
Radiopharmaceutical	Mr. James Ponto	RM: 1
Formulations		MA: 1
(Disc 1)		RC: 2
Health Physics and	Dr. Brigette McGhee	RIVI: 2
Recordkeeping (Disc 1)	,	RP: 2
Radiation Biology	Dr. Stamley M. Shaw	RP/I: 3
Disc 1-3		RB: 9
Late Effects of Ionizing Radiation	Dr. William R. Widmer	RP/I: 1
(Disc 1)		RB: 3
Radiation Safety in Prergnant and	Mr. James Ponto	RP/I: 1
Breastfeeding Patients (Disc 1)		RP; 3
Adverse Drug Reactions	Mr. James Ponto	RP/I: 1
(Disc 1)	1	RP: 2
		RB: 1
Radiopharmaceutical Updates	Dr. Richard Kowalsky	RP/I; 9
(Disc 1-3)		RB: 3
Blood Pool Imaging	Dr. Ronald Calahan	RP/I: 1
(Disc 1)		MA: 1
		RC: 2
Clinical PET	Dr. Laura Boles Ponto	RPT: 1
		RP: 1
		RC: 2
Nuclear Pharmacy Regulations (Disc 1-2)	Dr. Stanley M, Shaw	RP: 8
Radiopharmaceutical Chemistry (Disc 1-4)	Dr. Mark A. Green	RC: 16

Nuclear Pharmacy Certificate Program On-Campus Portion Clock Hours

Session	Instructor	
On Campus portion:	Dr. Kara Weatherman	RP/I: 34
		RP: 13
	1	MA: 10
		RB: 0
		RC: 8

Nuclear Pharmacy Certificate Program Instructional Staff

Dr. Stanley M. Shaw, Ph.D. Professor of Nuclear Pharmacy Purdue University West Lafayette, Indiana 47097

Dr. Paul Ziemer, Ph.D. Professor Emeritus of Health Physics Purdue University West Lafayette, Indiana 47097

Dr. Kara Weatherman, PharmD, BCNP, FAPhA Assistant Professor of Nuclear Pharmacy Purdue University West Lafayette, Indiana 47907

Ms. C. Anne Smith, M.S., B.C.N.P. Nuclear Pharmacy Program Director Purdue University West Lafayette, IN 47907

Mr. James A. Ponto, M.S., B.C.N.P. Division of Nuclear Medicine University of Iowa Hospitals and Clinics Iowa City, Iowa 52242 Brigette McGhee Staff Pharmacist Central Pharmacy Services, Inc Jacksonville, FL

Dr. William R. Widmer, D.V.M. Associate Professor of Diagnostic Imaging Department of Veterinary Clinical Sciences School of Veterinary Medicine Purdue University West Lafayette, Indiana 47907

Dr. Richard J. Kowalsky, PharmD, BCNP, FAPhA Associate Professor Pharmacy and Radiology University of North Carolina Chapel Hill, North Carolina 27599

Dr. Ronald Callahan, PhD Harvard Medical School - Associate Professor of Radiology Massachusetts General Hospital - Director of Nuclear Pharmacy Boston, Massachusetts 02114

Dr. Laura Boles Ponto, PhD Division of Nuclear Medicine University of Iowa Hospitals and Clinics Iowa City, Iowa 52242

Dr. Mark A Green, PhD Professor of Industrial and Physical Pharmacy Division of Nuclear Pharmacy Purdue University West Lafayette, Indiana 47907

NRC FORM 313A (ANP)

U.S. NUCLEAR REGULATORY COMMISSION

(3-2009)

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

Name of Proposed Authorized Nuclear Pharmacist

State or Territory Where Licensed

James H. CordonierH

Wyoming

PART I -- TRAINING AND EXPERIENCE (Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Skip to and complete Part II Preceptor Attestation.

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist

a. Classroom and Laboratory Training.

Location of Training	Clock Hours	Dates of Training*
Purdue University West Lafayette, IN & Long Distance Learning	85	July 2012 - August 2012
Purdue University West Lafayette, IN & Long Distance Learning	46	July 2012 - August 2012
Purdue University West Lafayette, IN & Long Distance Learning	23	July 2012 - August 2012
Purdue University West Lafayette, IN & Long Distance Learning	40	July 2012 - August 2012
Purdue University Long Distance Learning	21	July 2012 - August 2012
	Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning	Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University West Lafayette, IN & Long Distance Learning Purdue University Purdue University Purdue University Purdue University Purdue University Purdue University Purdue University

NRC FORM 313A (ANP) (3:2009)

PRINTED ON RECYCLED PAPER

PAGE 1

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609	110	June 11, 2012 - September 7, 2012
PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609	120	June 11, 2012 - September 7, 2012
PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609	250	June 11, 2012 - September 7, 2012
PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609	40	June 11, 2012 - September 7, 2012
PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609	40	June 11, 2012 - September 7, 2012
	PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609	PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609 PharmaLogic WY 3480 Trigood Drive, Ste 2 Casper, WY 82609

Total Hours of Experience: 560

Supervising Individual Tamiko Ushio, PharmD

c. Go to and complete Part II Preceptor Attestation.

(3,2009)

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II - PRECEPTOR ATTESTATION

N	0	to	
1.4	U	IC	

This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

Board Certification

I attest that

has satisfactorily completed the requirements in

Name of Proposed Authorized Nuclear Plarmacist

10 CFR 35.55(a)(1), (a)(2), and (a)(3) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

OR

Structured Educational Program

√ I attest that

James H. Cordonier II

has satisfactorily completed a 700-hour structured

Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for Pharmal ogic WY

□ ,

Nuclear Pharmacy or Medical Facility

49-27629-01MD

63 -

License/Permit Number

Name of Preceptor

Tamiko Ushio

Signature

Telephone Number

Date

Vanifa Ilshir

(307) 261-7000

09/12/2012

Wyoming State Board of Pharmacy

Meetings Home

Staff/Contacts Laws

Board Applications Fees Links Continuing Ed.

Newsletters Search Database FAQ

Search Pharmacy Database

Start New Search

The Wyoming State Board of Pharmacy certifies that it maintains the information for the license verification function of this website. performs daily updates to the website and considers the website to be a secure, primary source for license verification

Highlights

Search Results

License #	First Name
2504	1

Middle Name Last Name Cordonier

Expiration Issued 6/28/2012 12/31/2012 Status Discipline None

Contact Info

State Board Of Pharmacy Mary K. Walker, Executive Director

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Designed By: Saulid Solutions

From: (561) 416-0085 Jerry Strugala PHARMALOGIC 1 South Ocean Blvd. Suite 206 Boca Raton, FL 33432

CA

Origin ID: PHKA



SHIP TO: (817) 860-8100

Regional Administrator US NRC Region IV 1600 E LAMAR BLVD

ARLINGTON, TX 76011

BILL SENDER

Invoice # PO# Dept#

Ref#

Ship Date: 13SEP12 ActWgt: 1.0 LB CAD: 11223254NET3300

Delivery Address Bar Code

RECEIV

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3117

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Hill, Carol

From: gastrugala@gmail.com on behalf of Gerard Strugala

[strugala@optonline.net]

Sent: Tuesday, September 18, 2012 8:26 AM

To: Hill, Carol

Subject: Re: Request for Amendment of Materials License

Attachments: NRC Amendment Ltr 091812.pdf

Dear Ms. Hill,

I apologize for the incorrect referencing of the NRC RAM License number in my earlier correspondence.

I have attached a new cover letter, dated 18 September 2012, with the correct Radioactive Materials License Number we wish to amend.

If there are any other questions, please contact me directly.

Sincerely,

Gerard A. Strugala, RPh, BCNP PharmaLogic Holdings Vice President, Operations 732-539-9395 strugala@optonline.net

On Tue, Sep 18, 2012 at 8:55 AM, Hill, Carol < Carol. Hill@nrc.gov > wrote:

Good Morning,

We received the attached request for amendment of your Nuclear Materials License to add James Cordonier as an authorized user, however, you referenced two different license numbers in your letter. License No. 49-27629-01MD was referenced in the subject line and License No. 09-29398-01MD was referenced in the body of the letter. Which license are you requesting amended?

Carol L. Hill, Licensing Assistant

Direct: 817-200-1140

Toll Free: 1-800-952-9677

Fax: 817-200-1083

E-mail: <u>Carol.Hill@nrc.gov</u>

US Nuclear Regulatory Commission

1600 E. Lamar Blvd.

Arlington, TX 76011-4511

NRC FORM 532 (1-2012)	U. S. NUCLEAR REGULATORY COMMISSION
WICLEAN REGULATOR	DATE
(1-2012)	09/18/2012
海安安有	
NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Dhamadania WV. Inc	49-27629 - 01MD
Pharmalogic WY, Inc. ATTN: Tamiko Ushio, R.Ph.	MAIL CONTROL NUMBER
Radiation Safety Officer	579110
3480 Trigood Drive, Suite 2	LICENSING AND/OR TECHNICAL REVIEWER
Casper, Wyoming 82609	ch
This is to acknowledge the receipt of your	:
✓ LETTER and/or AF	PPLICATION DATED: 09/18/2012
The initial processing, which included an a	administrative review, has been performed.
✓ AMENDMENT ☐ TERMINA	TION NEW LICENSE RENEWAL
✓ There were no administrative omissions	identified during our initial review.
This is to acknowledge receipt of your a above. Your application is deemed timel final action has been taken by this office	pplication for renewal of the material(s) license identified ly filed, and accordingly, the license will not expire until
Your application for a new NRC license Please fill out NRC Form 531, located at	did not include your taxpayer identification number. the following link:
http://www.nrc.gov/re	ading-rm/doc-collections/forms/nrc531.pdf
Send the completed NRC Form 531, by	facsimile, to the following number: (301) 415-5387
	to our License Fee and Accounts Receivable Branch, in). You will be contacted separately if there is a fee issue
Varia and lighting has been engineed the	shave listed MAIL CONTROL NUMBER When

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV U. S. Nuclear Regulatory Commission DNMS/NMSB - B 1600 E. Lamar Boulevard Arlington, TX 76011-4511 (817) 200-1103 or (817) 200-1140

BETWEEN:		[FOR ARPB USE] INFORMATION FROM WBL		
Accounts Receivable	/Payable			
and		Program Code: 02500		
Regional Licensing B	ranches	Status Code: Pending Amendme		
		Fee Category: 2B 3C		
		Exp. Date:		
		Fee Comments:		
		Decom Fin Assur Reqd: N		
License Fee W	orksheet - License	Fee Transmittal		
A. REGION				
1. APPLICATION ATTAC	CHED			
Applicant/Licensee:	PHARMALOGIC WY, INC.			
Received Date:	09/14/2012			
Docket Number:	3038007			
Mail Control Number:	579110			
License Number:	49-27629-01MD			
Action Type:	Amendment			
2. FEE ATTACHED				
8				
Amount:				
Check No.:	<u>/</u>			
/				
3. COMMENTS				
	/			
		10011		
	Signed:	and of Hell		
	60 March 100 Mar	9/14/12		
	Date:	1/1 3/12		
B. LICENSE FEE MANA	GEMENT BRANCH (Check wi	hen milestone 03 is entered / /)		
Fee Category and Ar	nount:			
Correct Fee Paid. App.	olication may be processed for	ri		
Amendment:				
D				
Renewal:				
License:				
Elderise.				
3. OTHER				
2.				
	Signed:			

Date: