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NMSB2

January 09, 2006

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19046-1415

RE: New Radiation Safety Officer for License Number 37-28306-01, Docket Number 030-30892
Charles River Laboratories, Inc. – Malvern, PA (formerly Tektagen, Inc.)

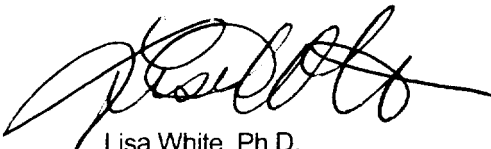
Dear Sir or Madam:

This letter is to notify the U.S. Nuclear Regulatory Commission that we are replacing our current Radiation Safety Officer, Harvey R. Schlesinger, Ph.D. with Douglas B. Brown, Ph.D.

Dr. Brown has more than ten years of experience working with radionucleotides both in the academic and research biotechnology fields. Throughout his graduate studies at Thomas Jefferson University (Philadelphia, PA), Dr. Brown served as his department's Assistant Radiation Safety Officer (1992-1995) and Radiation Safety Officer (1995-1998). Recently, Dr. Brown has completed over 40 hours of training at the Radiation Safety Academy (Gaithersburg, MD) and has received certificates for 'Radiation Safety Officer with LSC Option' and 'DOT & NRC Requirements for Shipping and Receiving Radioactive Materials'

If you need additional information please contact Harvey Schlesinger, Ph.D., Senior Director of Technical Services, at 610-640-4550 (extension 109) or hschles@bps.criver.com.

Sincerely Yours,



Lisa White, Ph.D.
General Manager

138227

NUCLEAR MATERIALS-002

Certificate of Training

Awarded To

Douglas B. Brown, Ph.D.

Recognizing completion of 5 days of specialized instruction in

Radiation Safety Officer with LSC Option

October 28, 2005

Presented By

Radiation Safety Academy
481 North Frederick Avenue, Suite 302
Gaithersburg, Maryland 20877

ABIH has awarded this course 4.5 CM Points, CM Approval #04-185
AAHP has awarded this course 32 Continuing Education Credits, 2003-00-018

Ray Johnson

Raymond Johnson, MS, PE, RSO, FHPS, CHP
Academy Director



Certificate of Training

This Certifies That

Douglas B. Brown, Ph.D.

has been trained, tested and successfully completed specialized instruction in

DOT & NRC Requirements for Shipping and Receiving Radioactive Materials

October 27, 2005

Presented By: **Sean M. Austin, Instructor**
Radiation Safety Academy

481 North Frederick Avenue, Suite 302, Gaithersburg, Maryland 20877
www.RadiationSafetyAcademy.com -- 301-990-6006

Presented For: **Charles River Laboratories, Inc.**

Presented At: **Gaithersburg, MD**

This certifies that the employee named on this certificate has been trained and tested in accordance with the training requirements of 49 CFR, Subpart H.


Employer's Signature

This certificate is valid for 24 months for ICAO/IATA and for three years for U.S. Department of Transportation and U.S. Nuclear Regulatory Commission or Agreement State Agencies.



Sean Austin, CHP
Senior Health Physicist

Douglas Bennett Brown



EDUCATION

Thomas Jefferson University College of Graduate Studies, Philadelphia, PA

Doctor of Philosophy, Biochemistry and Molecular Biology, June 2002

Thesis: The effects of ultraviolet radiation on elastin gene expression

Thomas Jefferson University College of Graduate Studies, Philadelphia, PA

Master of Science, Biomedical Chemistry, June 1995

Thesis: Ultraviolet radiation activates the human elastin promoter in transgenic mice: a novel *in vivo* and *in vitro* model of cutaneous photoaging.

Washington and Lee University, Lexington, VA

Bachelor of Arts, Chemistry, June 1992

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

PROFESSIONAL EXPERIENCE

Charles River Laboratories – Malvern, Biopharmaceutical Services

Scientist I, Methods Development, CRL-Malvern, Malvern, PA. March 2004 – present. This position assists the Study Director in the conduct of the study. This position may require acting as Study Director and is responsible for study conduct, Sponsor interaction, interpretation and reporting of study data, and regulatory compliance of assigned non-clinical research studies.

DakDak Photoaging Technologies/Argus Research, A Division of Charles River Laboratories

Scientist, DakDak Photoaging Technologies, Elkins Park, PA. December 2001 – February 2004.

This position represents an entry-level scientist. As Principal Investigator, act on behalf of the Study Director, but does not have responsibility for the conduct of the study. As a Study Director, under the direction of Senior Scientific Management, responsible for the conduct, management, Sponsor interaction, interpretation, and reporting of study data, and regulatory compliance of assigned non-clinical research studies.

DakDak Photoaging Technologies, LLC

Consultant. September 2001 – December 2001.

LABORATORY AND TECHNICAL SKILLS

- 2005-present Radiation Safety Officer, Charles River Laboratories, Inc., Malvern, PA
- 1994-2001 OSHA Assistant for Dept of Dermatology, TJU
- 1992-2001 Radiation Safety Assistant (1995-1998 Appointed Radiation Safety Officer) for Dept of Dermatology, TJU (including the monitoring, handling and disposing of wastes including ^3H , ^{14}C , ^{32}P , ^{33}P , ^{35}S). Original training Fall 1992 by Department of Radiation Safety, TJU with annual refresher courses through 2000. Safety training included proper documentation, handling, monitoring, surveying, cleaning after spills, and disposal of radioisotopes.
- Good Manufacturing Procedures
- Good Laboratory Procedures (including writing General Protocols, Standard Operating Procedures, Standard Technical Procedures, Qualification Protocols, Investigation Reports & Validation Reports)
- Animal husbandry (manage mice colonies, breeding and weaning animals, collecting tissue for genotyping)
- Cell-culture techniques (explants, transformation, transfection, cryopreservation)
- Electrophoresis of nucleic acids and proteins
- Genomic DNA and RNA isolation from cell cultures and animal tissues
- Immunohisto-chemistry (peroxidase and fluorescent labeling)
- Microbial Identification (16S rDNA, Gyrase B (Bacterial) and D2 LSU rRNA(Fungal))
- Polymerase Chain Reaction techniques (conventional with & without using ^{32}P , RT, quantitative fluorescence)

- Reporter gene assays (CAT assays using ^{14}C , Luciferase)
- Slot blot hybridization using ^{32}P
- Sequencing analysis (Genetic Analyzer 310)
- Southern and Northern (using ^{32}P) and Western blotting techniques

COMPUTER SKILLS

Microsoft Word, Excel, PowerPoint, Access, Publisher, ACT Database

AWARDS, CERTIFICATES, AND HONORS

2005 Radiation Safety Officer with LSC Option
2005 DOT & NRC Requirements for Shipping & Receiving Radioactive Materials
2000 Travel Award from American Society for Photobiology
2000 Thomas Jefferson University Alumni Travel Fellowship
1992 Travel Award from American Society for Photobiology
1990-1992 Robert E. Lee Research Fellowship

MEMBERSHIP

1997-2003 Associate Member of the American Society for Photobiology

PUBLICATIONS

Zelickson BD, Kist D, Bernstein E, **Brown DB**, Ksenzenko S, Burns J, Kilmer S, Mehregan, Pope K: Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative dermal remodeling device: a pilot study. *Arch Dermatol* 2004; 140(2): 204-209.

Bernstein EF, **Brown DB**, Schwartz MD, Kaidbey K, Ksenzenko SM: The polyhydroxy acid gluconolactone protects against ultraviolet radiation in an in vitro model of cutaneous photoaging. *Dermatol Surg* 2004; 30(2 Pt 1): 189-195; discussion 196.

Brown DB, Peritz AE, Uitto J, Gasparro FP: Ultraviolet-filtering properties of commonly used tissue cell culture plasticware. *Photodermatol Photoimmunol Photomed* 2001; 17(3): 126-129.

Bernstein EF, Lee J, **Brown DB**, Yu J, Van Scott E: Glycolic acid treatment increases type I collagen mRNA and hyaluronic acid content of human skin. *Dermatol Surg* 2001; 27(5): 429-433.

Bernstein EF, Kong SK, **Brown DB**, Kwak BC, Takeuchi T, Gasparro FP, Uitto J: The nitroxide Tempol affords protection against ultraviolet radiation in a transgenic murine fibroblast culture model of cutaneous photoaging. *Exp Dermatol* 2001; 10(1): 55-61.

Brown DB, Peritz AE, Mitchell DL, Chiarello S, Uitto J, Gasparro FP: Common fluorescent sunlamps are an inappropriate substitute for sunlight. *Photochem Photobiol* 2000; 72(3): 340-344.

Gasparro FP, **Brown DB**: Photobiology 102: UV sources and dosimetry – the proper use and measurement of UVR as a reagent. *J Invest Dermatol* 2000; 114: 613-615.

Bernstein EF, Kornbleuth S, **Brown DB**, Black J: Treatment of spider veins using a 10-millisecond pulse duration frequency-doubled Neodymium YAG laser. *Dermatol Surg* 1999; 25(4): 316-320.

Bethea D, Fullmer B, Syed S, Seltzer G, Tiano J, Rischko C, Gillespie L, **Brown D**, Gasparro FP: Psoralen photobiology and photochemistry: 50 years of science and medicine. *J Dermatol Sci* 1999; 19(2): 78-88.

Bernstein EF, Lee J, Lowery J, **Brown DB**, Geronemus R, Grossman MC, Lask G, Hsia J: Treatment of spider veins using the 595-nm pulsed-dye laser. *J Am Acad Dermatol* 1998; 39(5 Pt 1): 746-750.

Uitto J, **Brown DB**, Gasparro FP, Bernstein EF: Molecular aspects of photoaging. *Eur J Dermatol* 1997; 7: 210-214.

Bernstein EF, **Brown DB**, Takeuchi T, Kong SK, Uitto J: Evaluation of sunscreens with various sun protection factors in a new transgenic mouse model of cutaneous photoaging. *J Am Acad Dermatol* 1997; 37: 725-729.

Bernstein EF, Gasparro FP, **Brown DB**, Takeuchi T, Kong SK, Uitto J: 8-Methoxypsoralen and ultraviolet A radiation activate the human elastin promoter in transgenic mice: *in vivo* and *in vitro* evidence for gene induction. *Photochem Photobiol* 1996; 64(2): 369-374.

Bernstein EF, Underhill CB, Hahn PJ, **Brown DB**, Uitto J: Chronic sun-exposure alters both the content and distribution of dermal glycosaminoglycans: investigation by immunohistochemical staining, and confocal laser scanning microscopy. *Br J Dermatol* 1996; 135(2): 255-262.

Bernstein EF, Chen YQ, Kopp JB, Fisher L, **Brown DB**, Hahn PJ, Robey FA, Lakkakorpi J, Uitto J: Chronic sun-exposure alters the collagen of the superficial dermis: comparison of sun-protected and photoaged skin by Northern analysis, immunohistochemical staining, and confocal laser scanning microscopy. *J Am Acad Dermatol* 1996; 34(2 Pt 1): 209-218.

Bernstein EF, **Brown DB**, Urbach F, Forbes D, Del Monaco M, Wu M, Katchman SD, Uitto J: Ultraviolet radiation activates the human elastin promoter in transgenic mice: a novel *in vivo* and *in vitro* model of cutaneous photoaging. *J Invest Dermatol* 1995; 105(2): 269-273.

Katchman SD, Del Monaco M, Wu M, **Brown DB**, Hsu-Wong S, Uitto J: Topical glucocorticosteroids: assay of biological strengths in a novel transgenic mouse model. *Arch Dermatol* 1995; 131: 1274-1278.

Ledo I, Wu M, Katchman SD, **Brown DB**, Kennedy S, Hsu-Wong S and Uitto J: Glucocorticosteroids up-regulate human elastin promoter activity in transgenic mice. *J Invest Dermatol* 1994; 103(5): 632-636.

PRESENTATIONS

Comparative analysis of detection and quantitation of DNA by blot hybridization versus QF-PCR. ***DB Brown**, DLD Letham, LK Montgomery, MJ Hantman. 11th Annual Meeting of the Viral Vectors & Vaccines Conference. Williamsburg, VA. November 8-11, 2004. (workshop, talk)

Activation of the human elastin promoter by ultraviolet radiation can be decreased through the application of antioxidants. ***DB Brown**, FP Gasparro, and J Uitto. 62nd Annual Meeting of the Society for Investigative Dermatology. Washington, DC. May 9-12, 2001. (poster)

Intrinsic aging versus photoaging: a comparative histopathologic and immunohistochemical study. ***HM Ahmed**, SK Attiah FY Saleh, **DB Brown**, FP Gasparro, J Uitto, and MM El-Domyati. 62nd Annual Meeting of the Society for Investigative Dermatology. Washington, DC. May 9-12, 2001. (poster)

Investigation of p53 mutations: the analysis of exons 2-11 in squamous cell carcinoma from PUVA-treated skin. ***DH Suh**, AE Peritz, **DB Brown**, FP Gasparro, and J Uitto. 62nd Annual Meeting of the Society for Investigative Dermatology. Washington, DC. May 9-12, 2001. (poster)

Tropoelastin is transcriptionally activated by UVR. ***DB Brown**, AE Peritz, J Uitto, and FP Gasparro. 13th International Congress on Photobiology. San Francisco, CA July 1-6, 2000. (poster)

A 'better' sunlamp for relevant photobiology. ***FP Gasparro**, **DB Brown**, J Uitto, AE Peritz, S Chiarello, and DL Mitchell. 13th International Congress on Photobiology. San Francisco, CA July 1-6, 2000. (talk)

Tropoelastin is transcriptionally activated by UVR. ***DB Brown**, AE Peritz, J Uitto, and FP Gasparro. 1st Annual Meeting of the International Extracellular Matrix. Philadelphia, PA. June 10-14, 2000. (poster)

Tropoelastin is transcriptionally activated by UVR. ***DB Brown**, AE Peritz, J Uitto, and FP Gasparro. 61st Annual Meeting of the Society for Investigative Dermatology. Chicago, IL. May 10-14, 2000. (poster)

The nitroxide tempol affords protection against ultraviolet radiation as assayed using a transgenic mouse molecular model of cutaneous photoaging. ***DB Brown**, SK Kong, BC Kwak, T Takeuchi, J Uitto, EF Bernstein and FG Gasparro. 27th Annual Meeting American Society for Photobiology. Washington, DC. July 5-9, 1999. (talk)

The nitroxide tempol affords protection against ultraviolet radiation as assayed using a transgenic mouse molecular model of cutaneous photoaging. **DB Brown**, SK Kong, BC Kwak, T Takeuchi, J Uitto and ***EF Bernstein**. 60th Annual Meeting of the Society for Investigative Dermatology. Chicago, IL. May 5-9, 1999. (talk)

Ultraviolet radiation activates the human elastin promoter in transgenic mice: a cutaneous model of photoaging. ***DB Brown**, EF Bernstein, FP Gasparro and J Uitto. 48th Annual Symposium on the Biology of Skin. Snowmass, CO. August 18-23, 1998. (talk & poster)

Using transgenic mice to study cutaneous photodamage. ***DB Brown**, EF Bernstein, FP Gasparro and J Uitto. Delaware Valley Mouse Club. Thomas Jefferson University, Philadelphia, PA. June 22, 1998. (talk)

The effect of alpha hydroxy acids on viable epidermal thickness and collagen content. BC Kwak, T Takeuchi, ***DB Brown**, SK Kong, J Uitto and EF Bernstein. 58th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. April 23-27, 1997. (talk)

A rapid and sensitive model for evaluating compounds that protect against UVA-induced photoaging. *SK Kong, T Takeuchi, **DB Brown**, FP Gasparro, J Uitto and EF Bernstein. 58th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. April 23-27, 1997. (poster)

Evaluation of residual thermal damage to dermal collagen after laser resurfacing using computer-based image analysis. ***DB Brown**, AJ Burns, JM Kenkel, J Uitto and EF Bernstein. 58th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. April 23-27, 1997. (poster)

Laser resurfacing results in significant increases in the collagen of the subepidermal grenz zone of sun-damaged skin. *EF Bernstein, RE Fitzpatrick, **DB Brown** and J Uitto. 58th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. April 23-27, 1997. (talk)

Molecular aspect of photoaging. *J Uitto, **DB Brown**, and EF Bernstein. 12th International Congress on Photobiology—ICP'96. Vienna, Austria. September 1-6, 1996. (talk)

A novel, rapid and sensitive method for evaluating compounds offering protection against cutaneous photodamage. SK Kong, **DB Brown**, T Takeuchi, A Vu, PH Chang, J Uitto and *EF Bernstein. 24th Annual Meeting of the American Society for Photobiology. Atlanta, GA. June 15-20, 1996. (talk)

Human elastin promoter activity is up-regulated in multiple organs by UVB radiation administered to transgenic mice. ***DB Brown**, EF Bernstein, SK Kong, T Takeuchi, X Zhang and EML Tan. Biomedicine '96, Annual Meeting. Washington, DC. May 3-6, 1996. (poster)

Chronic sun-exposure alters both the content and distribution of dermal glycosaminoglycans. ***DB Brown**, PJ Hahn, CB Underhill, J Uitto and EF Bernstein. 57th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. May 1-5, 1996. (talk)

A novel, rapid and sensitive method for evaluating compounds offering protection against cutaneous photodamage. *SK Kong, **DB Brown**, T Takeuchi, A Vu, PH Chang, J Uitto and EF Bernstein. 57th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. May 1-5, 1996. (talk)

8-methoxypsoralen and ultraviolet A radiation activate the human elastin promoter in transgenic mice: *in vivo* and *in vitro* evidence for gene induction. *T Takeuchi, FP Gasparro, **DB Brown**, SK Kong, N Lopresti, T White, P Chang, J Uitto and EF Bernstein. 57th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. May 1-5, 1996. (poster)

UV-induced photoproduct formation on oligonucleotides – implications for topical antisense therapy. *FP Gasparro, K DeLeo, **DB Brown** and EF Bernstein. 57th Annual Meeting of the Society for Investigative Dermatology. Washington, DC. May 1-5, 1996. (poster)

Histological findings associated with Ultrapulse CO₂ laser resurfacing. *RE Fitzpatrick, EF Bernstein, **DB Brown**, *et al.* ASLMS, Annual Meeting, Orlando, FL. April 16, 1996. (talk)

Photochemical modification of specific bases in oligonucleotides. FP Gasparro, L Amici, J Park, **DB Brown** and EF Bernstein. 23rd Annual Meeting of the American Society for Photobiology. Washington, DC. June 19-21, 1995. (poster)

Alterations in extracellular matrix resulting from photoaging – immunohistochemistry and northern analysis. *EF Bernstein, K Resnick, **DB Brown** and J Uitto. 56th Annual Meeting of the Society for Investigative Dermatology. Chicago, IL. May 24-28, 1995. (talk)

Ultraviolet irradiation activates the human elastin promoter in transgenic mice: an *in vivo* and *in vitro* model of cutaneous photoaging. **DB Brown**, *EF Bernstein, M Del Monaco, S Katchman, M Wu, F Urbach, D Forbes and J Uitto. 56th Annual Meeting of the Society for Investigative Dermatology. Chicago, IL. May 24-28, 1995. (talk)

Confocal laser scanning microscopy reveals dramatic alterations of the extracellular matrix in photodamaged skin. *PJ Hahn, EF Bernstein, **DB Brown** and J Uitto. 56th Annual Meeting of the Society for Investigative Dermatology. Chicago, IL. May 24-28, 1995. (poster)

Topical glucocorticosteroids: assay of biological strengths in a novel transgenic mouse model. *SD Katchman, M Del Monaco, M Wu, **DB Brown**, S Hsu-Wong and J Uitto. 56th Annual Meeting of the Society for Investigative Dermatology. Chicago, IL. May 24-28, 1995. (poster)

Alterations in extracellular matrix resulting from photoaging – immunohistochemistry and northern analysis. *EF Bernstein, K Resnick, **DB Brown** and J Uitto. Annual Meeting for the American Society for Dermatologic Surgery. 1995.

1, 25- dihydroxyvitamin D3 upregulates human elastin promoter activity in the skin of transgenic mice. *S Katchman, **DB Brown**, M Wu, S Hsu-Wong and J Uitto. 55th Annual Meeting of the Society for Investigative Dermatology. Baltimore, MD. April 27-30, 1994. (poster)

Upregulation of human elastin promoter activity by glucocorticosteroids in transgenic mice. S Hsu-Wong, S Katchman, I Ledo, M Wu, ***DB Brown**, S Kennedy and J Uitto. 55th Annual Meeting of the Society for Investigative Dermatology. Baltimore, MD. April 27-30, 1994. (poster)

Glucocorticosteroid modulation of elastin gene expression. In "Sigma Xi, The Scientific Research Society [Abstract 12]." ***DB Brown** and J Uitto. Philadelphia, PA. April 21, 1994. (poster)

IN-HOUSE TRAINING ATTENDED

09/27/2005 cGMP Training 3rd Quarter – Change Control, Sheldon Krockner

04/06/2005 Chemical Hygiene for Research Laboratories Training – Edward A. Christman

04/06/2005 Bloodborne Pathogen Protection – Edward A. Christman

04/05/2005 Radiation Safety Training – Edward A. Christman

03/31/2005 GMP/GLP Training 2nd Quarter – Nonconformances, Investigations, Repeat Tests, and OOS Controlled Documentation, Mike Milner

02/28/2005 GMP/GLP Training 1st Quarter – Current Good Manufacturing Practices, Sheldon Krockner, Mike Milner

01/21/2005 Aseptic Technique Training – Allison Huesgen

12/02/2004 GMP/GLP Training 4th Quarter – Sarbanes-Oxley, Rob Collins, Sharon McQuaid

09/14/2004 GMP/GLP Training 3rd Quarter – Regulatory Inspections, Mike Milner, Sharon McQuaid

06/14/2004 GMP/GLP Training 2nd Quarter – Training Documents, Erika Synder, Sharon McQuaid

03/17/2004 GMP/GLP Training 1st Quarter – GMP v. GLP, Erika Synder, Sharon McQuaid

05/13/2003 Animal Welfare Training, Becky Altmann-Reilly

03/10/2003 Bloodborne Pathogen Training, Julian Gulbinski

02/13/2003 Regulatory Inspection Readiness Training, Krista M Cole, Cynthia M Kelsch, Jennifer A Strauss

This is to acknowledge the receipt of your letter/application dated

11/9/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Approved. 37-28306-1
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 138227.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.