

U.S. Nuclear Regulatory Commission Region I, Nuclear Materials Branch 2 Division of Nuclear Materials Safety 475 Allendale Road King of Prussia, PA 19406

(NMSB 3)

License Numbers: 37-00282-04, 37-00282-05

03029439

Subject: License Amendment for the Appointment of an interim Radiation Safety Officer

Dear Sir or Madame,

SmithKline Beecham Pharmaceutical d/b/a GlaxoSmithKline wishes to amend its byproduct material and irradiator Nuclear Regulatory Commission licenses to reflect the appointment of Richard Rebar as the interim Radiation Safety Officer replacing Gail E. Martin who will retire on 5 July 2006.

Mr. Rebar has been with the company 25 years in a number of positions of increasing responsibility. His work as the Assistant Radiation Safety Officer from 1987-1997 and his continued involvement in the development of Global Radiation Safety Standards for GSK has provided the experience needed to perform the duties of the Radiation Safety Officer.

Attached please find the resume of Richard Rebar as well as the signed Delegation of Authority. The current Radiation Safety Staff remains intact. Mr. Rebar will report to Dr. Eileen Hotte, Director, Environment, Health, and Safety.

Should you have any questions, please call me at (610) 270-7646, or Eileen Hotte at (610) 270-7856.

Sincerely,

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Frederick J. Simpson Vice President, US Site Operations, Pharmaceutical and R&D GlaxoSmithKline 709 Swedeland Road Mail Code UW 2332 King of Prussia, PA 19406 GlaxoSmithKline 709 Swedeland Road P.O. Box 1539 King of Prussia, PA 19406-0939

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Delegation of Authority Radiation Safety Officer

Memorandum:	To: File
From:	Frederick J. Simpson
Subject:	Delegation of Authority for Radiation Safety Officer

Richard Rebar has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of byproduct material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of byproduct material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.

Ledence

Frederick J. Simpson Vice President, US Site Operations, Pharmaceutical and R&D

June 21, 2006

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RICHARD REBAR

EDUCATION:

Bachelor of Arts (B.A) in Microbiology (1975) Rutgers University, New Brunswick, NJ

Masters in Science (M.Sci.) in Pharmacology (1987) Philadelphia College of Pharmacy and Science, Philadelphia, PA

EXPERIENCE:

GlaxoSmithKline Research & Development

8/03 - present Manager Biosafety Research and developemnt World-Wide, EHS – Direct management of all aspects of the R&D Biosafety Program for the Upper Merion and Upper Providence R&D sites. Co-ordinate and harmonize the Biosafety Program for all R&D sites World-Wide. Provide suport to R&D EHS staff at UM/UP for all safety programs.

GlaxoSmithKline Corporate

1/92 - 8/03 Manager Global Audits, Corporate Environment, Health & Safety (CEHS)

Management of the GSK CEHS Performance Assessment Program including scheduling of audits, conducting EHS audits including assessing radiation safety programs at all sites, maintaining the audit database, compiling the audit data and evaluating the program's effectiveness. Responsible for developing the GSK global standards on Radiation Safety and Biosafety. Responsible for developing strategies for improving safety performance, developing of GSK-wide safety initiatives, new programs (auditing of contract manufacturers) and safety performance assessment methodologies. Experienced in European, UK, and many International safety regulations.

- Smith Kline & French Laboratories
- 2/90-2/92 <u>Manager Biosafety</u> Management of all aspects of the SB R&D Biosafety Program. Chaired the R&D Biosafety and Institutional Biosafety Committees.
- 2/89-2/90 <u>Asst. Manager Biosafety</u> / <u>Asst. Radiation Safety Officer</u> Management of all aspects of SK&F Biosafety Program - Assisted in the management of the Radiation Safety Program.
- 9/88-2/89 Biosafety/Radiation Safety Coordinated all aspects of the Biosafety and Radiation Safety Programs.
- 1/87-9/88 Radiation Safety Coordinator Coordinated all aspects of the Radiation Safety Program.
- 9/82-1/87 <u>Research Scientist</u> Research involved purification and biochemical characterization of membrane receptor proteins, use of radioactive materials as a Principal Radiation User using mCi quantities of P³², I¹²⁵, S³⁵, P³³, H³ and C¹⁴.
 - Frederick Cancer Research Center, Ft. Detrick, Frederick, MD:
- 5/81-8/82 <u>Research Scientist</u> Research involved purification and characterization of tumor antigens and monoclonal antibodies.
 - George Washington Univ. at the VA Medical Center, Wash., DC:
- 9/79-5/81 <u>Research Scientist</u> Research involved mechanisms of hemostasis disorders.
 - Schering-Plough Corp.- Bloomfield, NJ
- 2/78-9/79 Microbiologist Coordination and running of an antibiotic fermentation laboratory.
- 8/76-2/78 Asst. Radiation Safety Officer Coordination of all aspects of the Radiation safety program.
- 4/75-8/76 <u>Pathogenic Microbiologist</u> Analysis of specimens for pathogenic microorganisms for Animal Health.

ADDITIONAL GRADUATE STUDIES:

Hood College (Biochemistry) George Washington Univ. Medical School (Biochemistry) Rutgers University (Microbiology) Rutgers University (Radiation Sciences) Ohio State University, Ergonomics Short Course/Univ. of Wisconsin, Ergonomics in the Workplace

PROFESSIONAL EXPERIENCE:

Rich has been with GlaxoSmithKline Beecham for 24 years and started as a Research Scientist performing Molecular Pharmacology Research. Rich has a total of 30 years of experience in both pharmaceutical research and basic research. He has spent the last 16 years in the health and safety field concentrating on Biosafety, Radiation Safety, Ergonomics and General Safety issues. He has conducted thyroid scans, radiation swipe testing, X-ray machine calibration and leak testing and radiation emergency response. Rich developed Radiation safety Training programs for GSK as well as writing several Radiation Safety Manuals. Rich was a member of the R&D Radiation Safety Committee at GSK for 15 years (1982-1997) and was a member of the Health Physics Society. Rich is a registered Biosafety Professional (with the American Biological Safety Association [ABSA]) and is an ISO and OHSAS Certified Environment & Safety Auditor by SGS International Certification Services. Rich has served as Secretary of ABSA as well as Chair of the Technical Review Committee for ABSA and President of the Mid-Atlantic Biological Safety Association (MABSA). He is currently serving as Chair of the Registration Review Board and as a member of the Technical Review Committee, Re-cerifiction Committee, OSHA Alliance team and the Certification Review Board for the American Society for Microbiologists.

PROFESSIONAL AFFILIATIONS

Member American Biological Safety Association (ABSA) Member Mid-Atlantic Biological Safety Association (MABSA) Member American Society for Microbiologists (ASM)

OTHER QUALIFICATIONS

- Registered Biological Safety Professional (RBP)
- Certified Biological Safety Professional (CBSP)
- Certified Lead Auditor ISO 14001 and OHSAS 18001

PUBLICATIONS:

R. Rebar, Biosafety Needs of laboratotries in Developing Nations, Lab Animal Volume 29, No. 6, (June 2000)

R. Rebar, The Art of Biosafety Auditing in Industry, Applied Biosafety, Journal of the American Biological Safety Association, Volume 7, No.3 (2002)

R. Rebar and H. Moriyama, Biosafety Compliance: A Global Perspective, in Biological safety: Principles and Protectices, 3rd Edition, ASM Press Washington, DC, D. Flemingand D. Hunt Editors (2000)

J.M. Stadel, R. Rebar and S.T. Crooke. Alkaline Phosphatase Relieves Desensitization of Adenylyl Cyclase-Coupled Beta-Adrenergic Receptors in Avian Erytirrocyte Membranes. Biochemical Journal. 252:771-776 (1988)

J.M. Stadel, R. Rebar and S.T. Crooke.. Catecholanine-Induced Desensitization of Adenylate Cyclase Coupled Beta Adrenergic Receptors in Turkey Erythrocytes: Evidence for a Two-Step Mechanism. Biochemistry, 26:5861.(1987)

R.G.L. Shorr, L. Gottlib, A. Varrichio, R. Rebar, M.W. Strohsacker, M. Minnich and S.T. Crooke, Purification of Beta-Adrenergic Receptor from Rabbit Lung Plasma Membranes. (1987)

J.M. Stadel, R. Rebar, R.G.L. Shorr, P. Nambi and S.T. Crooke, Biochemical Characterization of Phosphorylated B-Adrenergic Receptors from Catecholamine-Desensitized Turkey Eryhtrocytes, Biochemistry, 25:3719-3724 (1986)

Shorr, R.G.L., McCaslin, D.R., Strohsacker, M.W., Alianel, G., Rebar, R., Stadel, J.M., Crooke, S.T., Molecular Structure of the B-Adrenergic Receptor. (1986)

R.G.L. Shorr, M. Minnich, L. Gotlib, A. Varrichio, M.W. Strohsacker, M. Clark, R. Rebar, and S.T. Crooke, Molecular Processing of Beta Adrenergic receptors. (1986)

M.W. Strohsacker, M. Minnich, L. Gotlib, A. Varrichio, J.M. Stadel, R. Rebar, G.E. Menzel, S.T. Crooke and R.G.L. Shorr, Biochemical Characterization of the heterogeneous B-1 Adrenergic Receptor Forms of the Turkey Red Blood Cell, (1985)

R.GL. Shorr, M.W. Strohsacker, R. Rebar, R.J. Lefkowitz, M.G. Caron and S.T. Crooke in Progress in HPLC: Gel Permeation of Proteins and Peptides. H. Parvez, S. Parvez and Y. Kato, ed. NY Science Press, Utrecht, Holland.(1983)

R.G.L. Shorr, F. Marshall, M. Clark, E. Kloxzewski, I. Stadel, R. Rebar, I. Bloom and S.T. Crooke. Heterogeneity of beta- adrenergic receptors in turkey erythrocyte and reticulocyte plasma membranes. ASCB San Antonio, Texas.(1983)

R.G.L. Shorr, M.W. Strohsacker, R. Rebar, R.J. Lefkowitz, M.G. Caron and S.T. Crooke. Membrane-bound hormone receptor purification and characterization by HPLC. In Progress in HPLC Vol.1, pp.9-26. H. Parvez, S. Parvez and Y. Kato, eds. NY Science Press, Utrccht, Holland.(1983)

Richard Rebar -CV

Undergraduate Courses:

Microbiology Courses: Rutgers University, New Brunswick, NJ)

General Microbiology + lab Microbiology and Molecular Genetics + lab Immunology + lab Molecular Biology of Microorganisms Pathogenic Bacteriology I Pathogenic and Diagnostic Bacteriology 11+ lab Virology and Tissue Culture + lab

Other Science Courses: Rutgers University, New Brunswick, NJ)

General Biology + lab Ecology + lab Biochemistry + lab **Radiation Biology** Cytology General Chemistry + lab Organic Chemistry + lab Physics + lab **Modern Biological Instrumentation**

Graduate Courses:

Statistics - Rutgers University, New Brunswick, NJ
Biochemistry - Rutgers University, New Brunswick, NJ
Advanced Biochemistry - George Washington Medical School, Washington, DC
Advanced Biochemistry I - Hood College, Frederick, MD
Advanced Biochemistry II - Hood College, Frederick, MD
Applied Health Physics - Rutgers University, New Brunswick, NJ
Fundamentals of Electronics - Rutgers University, New Brunswick, NJ
General Microbiology - Rutgers Institute of Microbiology, Piscataway, NJ
Seminar in Microbial Genetics - Rutgers Institute of Microbiology, Piscataway, NJ
Cancer - Rutgers Institute of Microbiology, Piscataway, NJ
Pharmacology - Rutgers Medical School, Newark, NJ
Cell Structure and Function - Hood College, Frederick, MD
Scientific Methodology and Experimentation - Hood College, Frederick, MD
Statistics for Experimenters, Hood College, Frederick, MD

Advanced Pharmacology:

Neuropharmacology I - Philadelphia College of Pharmacology & Science, Phila., PA Autonomic Pharmacology II - Philadelphia College of Pharmacology & Science, Phila., PA Cardiovascular Pharmacology II - Philadelphia College of Pharmacology & Science, Phila., PA Advanced Topics in Pharmacology - Philadelphia College of Pharmacology & Science, Phila., PA

Masters's Thesis:

Biochemical Characterization of Phosphorylated Beta-Adrenergic Receptors from Desensitized Avian Erythrocytes

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

Atceived 6 (19/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Artens. 37-00232-04 / 37-00282-05 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** $\frac{139027}{139028}$ When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI) (6-96) Sincerely, Licensing Assistance Team Leader