

Ronald M. Califre Senior Vice President Head, U.S. Operations Research and Development NOVARTIS INSTITUTE FOR BIOMEDICAL RESEARCH Novartis Pharmaceuticals Corporation One Health Plaza East Hanover, New Jersey 07936-1080

Tel (862) 778-2394 Fax (973) 781-2407 Internet: ronald.califre@novartis.com

January 10, 2008 Mr. Samuel Collins U.S. Nuclear Regulatory Commission Region 1 Nuclear Materials Safety and Safeguards Branch 475 Allendale Road King of Prussia, PA 19406-1415 030 053 57

Re: Change of RSO for License No. 29-08978-02

Dear Mr. Collins,

This letter is to inform the Nuclear Regulatory Commission that Mr. George Stone will no longer perform the duties of Radiation Safety Officer for Novartis Pharmaceuticals Corporation for our NRC radioactive material license 29-08978-02 as of January 15, 2008. Mr. Richard Brack will assume all responsibilities of the Radiation Safety Officer on an ad interim basis for Novartis Pharmaceuticals Corporation at that time.

Mr. Brack has over 17 years of experience with Novartis Pharmaceuticals Corporation and the predecessor Sandoz Pharmaceuticals Corporation. This experience has included work as an authorized user of radioactive materials while a laboratory scientist. It also includes oversight of laboratory safety programs as a health and safety manager of the Health, Safety, Environment & Business Continuity Department. Mr. Brack's resume is enclosed.

We will advise you immediately when a full time Radiation Safety Officer is appointed. In the meantime, if you have any questions regarding this change please contact Mr. Gregory King at 862-778-0495.

Thank you for your attention in this matter.

Sincerely utre Califre nior Vice President Research & Development Operations

141583

NMSS/RGN1 MATERIALS-002

Encl.

## **RICHARD BRACK**

.\*



## EXPERIENCE:

January 2001 Present	NOVARTIS, East Hanover, NJ - Developing new skills in the science of life. <u>Senior Safety Specialist</u> – East Hanover Site Biosafety Officer and East Hanover Site Transportation Safety Advisor for R&D. Received two Business Excellence Awards; one for developing a system to track training compliance the other for implementing a Life Safety Alarm program.
January 1998 - Dec. 2001	NOVARTIS, Summit, NJ - Developing new skills in the science of life.
	Scientist 3 – New technique development and implementation - Transplantation
January 1997- January 1998	NOVARTIS, East Hanover, NJ - Developing new skills in the science of life.
	<u>Scientist B</u> - High Capacity Drug Screening - Transplantation Planning, implementing, analyzing and reporting results from high capacity drug screening programs. Overcame problems, prioritized interactions of different departments and individuals to set up a collection and reimbursement program for the major component used in development of a high capacity screening program.
July 1991 - Dec. 1996	SANDOZ PHARMACEUTICALS, E. Hanover, NJ - An ethical pharmaceutical manufacturer
	<u>Scientist-A</u> - Screen compound libraries and combinatorials for Oncology. Ran assay's, analyzed data via Microsoft Excel and reported results.
	Scientist A – Responsible for protein purification while part of Central Technologies,
	Mechanisms Receptors Group, Adhesion Biology. Protein purification including: optimization, scale up, maintenance, and trouble shooting while producing mg to g quantities of proteins.
	<u>Scientist A</u> – Responsible for process development of monoclonal antibody production in VERAX bioreactors in the GMP Monoclonal Antibody Pilot Plant.
May 1990 -	PAINTBALL DEPOT, Mansfield, NJ - An outdoor recreational company.

<u>Founder and Manager</u> - Marketing, negotiation and strategic planning. Through a high degree of attention to procedures we have made this one of the safest game parks in the country. Eighteen-year exceptional safety record.

## EXPERIENCE: (continued)

April 1989

April 1989 - CLINICAL SCIENCES INC., Whippany, NJ - Immunodiagnostic reagent May 1990 manufacturer

<u>Slide Production Supervisor</u> In charge of silk-screened slide production and inventory maintenance of raw materials, equipment and finished slides. Reduced product rejection rate 15% by retraining employees and instituting new maintenance procedures. Conducted research with Borrelia burgdorferi for development of an assay for Lyme disease.

May 1986 - SLOAN-KETTERING, New York, NY - Cancer Research Institute

<u>Research Studies Assistant</u> Used molecular biology to conduct studies on HIV. Tracked viral mutation during the course of individual patient's disease and isolated strains from autopsies and biopsies. Founding member of Memorial Hospital and Sloan-Kettering Biological Safety committee.

**EDUCATION:** COLORADO STATE UNIVERSITY, Fort Collins, CO Bachelor of Science, Biochemistry, 1985

> FAIRLEIGH DICKINSON UNIVERSITY, Madison, NJ Pharmaceutical-Chemical Studies (MBA), matriculated (not completed)

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

includes an administrative review has been performed.

**Amena**, 29-08978-07 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.

141583 Your action has been assigned Mail Control Number \_ 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