

Mr. Steven Courtenmanche Division of Nuclear Material Safety U.S. Nuclear Regulatory Commission 475 Allendale Rd King of Prussia, PA 19406-1415

Re: License No. 06-30933-02

03036925

Dear Mr. Courtnemanche;

I am currently the Site Head and Medical Director of Pfizer New Haven Clinical Research Unit. I am writing to request an amendment to our radiation activity license to appoint Dr. Subhashis Banerjee as Radiation Safety Officer for the facility, as Dr. Irina Kaplan is moving to a different department at Pfizer effective September 21, 2006. Please find attached Dr. Banerjee's CV and the letter from his previous place of employment describing his experience with handling radioactive materials. Dr. Banerjee will be attending a week long RSO training on September 11-15 at Radiation Safety Associated in Hebron, CT.

If you have any questions regarding this issue if you required any additional information, please don't hesitate to contact me.

Sincerely,

Dr. Howard Uderman **Medical Director**

Site Head, Pfizer Clinical Research Unit



Must be typed and all sections must be completed.

| INVESTIGATOR ONE PAGE CV | | | | | | | |
|--|--|---|---|--|-------------|--|--|
| Full Name: Banerjee | Subhashis | | | Date: | 21/Sep/2005 | | |
| Last Name | First Name | | Middle Ini | tial | dd/mmm/yyyy | | |
| Study Site Affiliation: (e.g., Principal | Investigator, Sub Investigator | , Coordinator) | | | | | |
| ☑ Principal Investigator ☑ Sub Investigator ☐ Coordinator | | | | | | | |
| Professional Mailing Address: (Include institution name.) | | | Study Site Address: (Include institution name.) | | | | |
| Pfizer New Haven CRU One Howe Street New Haven, CT 06511 | Pfizer New Haven CRU One Howe Street New Haven, CT 06511 | | | | | | |
| Telephone: (203) 401-0231 | Telepho | Telephone: (203) 401-0100 | | | | | |
| Academic Ovalifications (most curre | nt date first) | ······································ | · | | | | |
| Degree/Certification | Date (mmm/yyyy) | Institution, Co | untry | ************************************** | | | |
| Internal Medicine | Oct/2004 | American Board of Internal Medicine, USA | | | | | |
| Residency in Internal Medicine | Apr/2004 | Saint Vincent Hospital, Worcester, MA, USA | | | | | |
| Fellowship in Clinical Immunology/ | Mar/1985 | All-India Institute of Medical Sciences, New Delhi, India | | | | | |
| Rheumatology | heumatology | | | | | | |
| M.D. (Residency in Internal Medicine) | Mar/1982 | Christian Medical College Hospital, Vellore, India | | | | | |
| M.B.B.S. (Medical School) | Jan/1979 | | al College, Vellore, Ir | | | | |
| Current and Previous 4 Relevant Pos | | ppointments (mo | st current date first) | : | | | |
| Dates In Years | <u>Title</u> | Institution/Con | | | | | |
| April 2005-present | Associate Director | Pfizer CRU, New Haven, CT, USA | | | | | |
| July 2004-March 2005 | Asst. Prof. of Medicine | UMass Memorial Medical Center, Worcester, MA, USA | | | | | |
| June 1993-Nov 2004 | Sr. Principal Scientist/ | Abbott Bioresearch Center/BASF Bioresearch Corporation, | | | | | |
| 0 1 1000 15 1000 | Grp Leader | Worcester, MA, USA | | | | | |
| October 1988-May 1993 | Senior Research Fellow Research Fellow | Shriners Hospital, McGill University, Montreal, Canada | | | | | |
| April 1985-September 1988 Research Fellow Mayo Clinic, Rochester, MN, USA | | | | | | | |
| Brief Summary of Relevant Clinical Research Experience: | | | | | | | |
| Principal investigator/subinvestigator on ten protocols at New Haven CRU. Patient care expertise in Internal Medicine, Rheumatology and Clinical Immunology. Active involvement in clinical trial design and assessment of trial results at Abbott Laboratories/BASF Corporation. Extensive experience in preclinical research and drug discovery at Abbott Laboratories/BASF Corporation, including biomarker development, in vivo studies in animal models, pharmacology, cellular techniques, and assay development. | | | | | | | |
| License/ID Number: 043356 | | Licensed | | Connecticu | rt | | |
| | • | State/Pro | vince/Country: | | | | |
| | | | Signature Date: | | | | |
| Section of the sectio | | | | | | | |
| | | | | | | | |
| (Signature required for ALL Investigators) | | | | | | | |
| NOTE: CV MUST BE LIMITED TO ONE PAGE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. PLEASE NO ATTACHMENTS, AND NO TEXT ON THE REVERSE SIDE. | | | | | | | |

| This is to acknowledge the | e receipt of your letter/application dated | |
|-----------------------------|---|--|
| includes an administrative | , and to inform you that the initial processing which review has been performed. | |
| | trative omissions. Your application was assigned to a asse note that the technical review may identify additional ditional information. | |
| Please provide to this o | office within 30 days of your receipt of this card | |
| | been forwarded to our License Fee & Accounts Receivable ou separately if there is a fee issue involved. | |
| | gned Mail Control Number 139326. out this action, please refer to this control number. 337-5398, or 337-5260. | |
| NRC FORM 532 (RI) (6-96) | Sincerely, | |

--