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May 19, 2008

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P-7

Dr. Thomas Thompson  
U.S. Nuclear Regulatory Commission Region 1  
Nuclear Materials Safety and Safeguards Branch  
475 Allendale Road  
King of Prussia, PA 19406-1415

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Re: More information regarding Mail Control No. 141583

Dear Dr. Thompson,

This letter is a follow up to the request by the Nuclear Regulatory Commission for additional information regarding Mr. Richard Brack's capabilities as the proposed Radiation Safety Officer for the byproduct materials authorized on Novartis Pharmaceuticals Corporation's NRC radioactive material license 29-08978-02.

We are very confident that Novartis will maintain a strong radiation safety program under Mr. Brack's leadership. First and foremost, Mr. Brack's experience in managing health and safety programs in the R&D environment is a valuable foundation for leading our radiation safety efforts. This management experience will be bolstered by comprehensive technical training that is regarded as an industry standard. Moreover, the current scope of our program is significantly smaller than permitted by our type A license. Lastly, Mr. Brack will have considerable technical expertise readily available to him from fellow department members.

At Novartis, we presently have a small and very manageable radiation safety program even though we have a type A license. The majority of the work conducted by our scientists involves the use of C-14 and H-3 with a few cases of small amounts of I-125. I-125 is purchased as a component of an assay kit (usually 250 uCi amounts) and is completely used up shortly after receipt. C-14 and H-3 are purchased in mCi amounts, with the exception an occasional order of 1,000 mCi for use by our Radiosynthesis Department. At our recent Radiation Safety Committee meeting, we inquired whether there were any planned significant changes in either the types or amounts of byproduct material used. All representatives agreed that there should be no changes in type or amounts used for the foreseeable future.

The technical expertise of the Novartis staff supporting Mr. Richard Brack is extensive. Mr. Brack is working under the guidance of the Executive Director of Health, Safety, Environment & Business Continuity, Gregory King, who was formerly the Novartis Radiation Safety Officer and who is certified by the American Academy of Health Physics in the comprehensive practice of Health Physics. Mr. Brack is also able to draw on the experience of Kevin Readie, Manager,

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HSE&BC, who has over 5 years experience in the day to day activities of radiation safety program management.

Mr. Brack has registered for the Radiation Safety Officer Training Program at Oak Ridge Associated Universities (ORAU). Mr. Brack will be attending the course scheduled to take place June 23 - 27, 2008. Specifically, the Oak Ridge course addresses types A, B, and C licenses with emphasis on type A broad scope licenses, and would give Mr. Brack additional background for assuming the role of Radiation Safety Officer at Novartis Pharmaceuticals. In addition to attending the course, Mr. Brack will prepare by reviewing the Novartis Radiation Safety Program and will be prepared to discuss recommendations for improvements with the course facilitators.

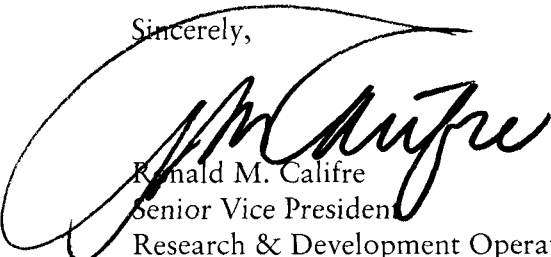
Mr. Brack discussed downgrading to a type B license with the radiation safety committee members at the March 19<sup>th</sup> 2008 committee meeting. The committee felt strongly that a type A license should be maintained. The active involvement and strong partnership between the RSO and the radiation safety committee has led to the maintenance of an exemplary radiation safety program at Novartis, with no findings during any of the NRC inspections since the formation of Novartis in 1996. Mr. Brack has been part of and contributed to the strong Novartis radiation safety performance, both as a member of the research department prior to 2001 and as a member of the safety department thereafter. Mr. Brack intends to continue this exemplary performance as Radiation Safety Officer. Also, my stewardship as the responsible authority will continue; bringing continuity to the historically strong program performance at Novartis.

Mr. Brack is reviewing the Novartis type A license and is investigating down grading the quantities of byproduct materials listed on the license. Mr. Brack will discuss downgrading the quantities at the fourth quarter Novartis Radiation Safety Committee meeting - where a decision will be made on whether to lower the existing limits (but still maintaining the Type A license).

Mr. Brack's leadership role as the proposed Radiation Safety Officer was discussed with committee members at the Wednesday, March 19, 2008 Radiation Safety Committee meeting. Committee members are supportive of Mr. Brack assuming the role of Radiation Safety Officer. It is felt that the Novartis Radiation Safety Program would be strongly supported by his leadership.

Thank you for your consideration of this matter. If you have any questions, please contact Mr. Gregory King, CHP at 862-778-0495.

Sincerely,



Ronald M. Califre  
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