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Memorandum

To G. Van Buskirk, D. Hauser, A. Rummelt, K. Ronlund, T. Koestler, A. Adly, W. Yetter

Copy To R. Somma

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Concerning Recognition for Russ Somma

On November 3 the International Society for Pharmaceutical Engineering (ISPE) and the FDA Center for Drug Evaluation and Research (CDER) and the FDA Office of Regulatory Affairs (ORA) received Vice President Al Gore's "Hammer Award." Specifically, the award is for the partnership between FDA and ISPE which resulted in the SUPAC equipment guidance document for immediate release solid dosage forms. This ISPE Committee was headed by Russ Somma from Novartis.

The Hammer Award is given to federal employees and their partners who have advanced the Vice President's National Performance Review goals of cutting red tape, improving service to customers, and helping build a better and more cost effective government. The SUPAC guidance and the associated equipment guidance document provides substantial regulatory relief in filing of change information. The document is expected to save industry millions of dollars in developing and implementing change procedures.

In his remarks upon accepting the award for ISPE, Larry Kranking, President ISPE, recognized the contributions of Russ Somma in managing this ISPE-FDA team. While Russ was quick to give the success to his ISPE team, members of his team who approached me after the ceremony emphasized that it was only through the leadership and tenacity of Russ that the group was able to deliver its objective completely and on time. Joseph X. Phillips, Deputy Regional Food and Drug Director, Mid-Atlantic Region, expressed to me that Russ was the driving force within ISPE for the completion of the document. Mr. Phillips said that he feels it is great that a large company such as Novartis was able to offer Russ as a resource for this important work. He feels that it shows a high level of commitment on the part of Novartis. Earlier this year I received a letter of commendation for Russ from Susan M. Setterberg, regional Food and Drug Director, Mid-Atlantic Region.

In other ceremonies at the ISPE Annual Meeting, the SUPAC Steering Committee headed by Russ received the ISPE Committee of the year award. It was also announced that the ISPE will receive a special recognition award from the FDA later this month. Accepting this award on behalf of the ISPE will be Bob Best, Executive Director ISPE, Larry Kranking, President of ISPE and Russ Somma from Novartis.

Please join me in expressing congratulations to Russ for recognition of his service to our industry and in representing Novartis in such a positive way.