MEMORANDUM

DATE: April 5, 2006

TO: Jason D. Brodsky
Acting Associate Commissioner
Office of External Relations
Food and Drug Administration

THROUGH: Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Igor Cerny, Pharm.D. /s/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Mr. Marshall Loeb

I am writing to request a waiver for Mr. Marshall Loeb, a consultant Patient Representative to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official when it is determined that "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Mr. Loeb a waiver under 18 U.S.C. §208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee, or any other person whose interests are imputed to the employee under 18 U.S.C. §208, has a financial interest. Since Mr. Loeb is a special Government employee, he is under a statutory obligation to refrain from participating in an official capacity in any particular matter having a direct and predictable effect on a financial interest attributable to him, his spouse, minor

child, or general partner; an organization or entity for which he serves as an officer, director, trustee, general partner, or employee; and, a person with whom he is negotiating for, or as an arrangement concerning, prospective employment.

Mr. Loeb has been asked to participate in all official matters concerning supplemental new drug application (NDA) 20823, SE1-016, Exelon® (rivastigmine tartarte) Capsules (1.5 milligrams (mg), 3.0 mg, 4.5 mg, and 6.0 mg), sponsored by Novartis Pharmaceuticals Corporation, a subsidiary of Novartis AG, for the proposed indication of the treatment of mild to moderate dementia associated with Parkinson's disease. This matter is coming before the Peripheral and Central Nervous System Drugs Advisory Committee for consideration.

The function of Peripheral and Central Nervous System Drugs Advisory Committee, as stated in its charter, is to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurological diseases and make appropriate recommendations to the Commissioner of Food and Drugs.

Mr. Loeb has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described previously. Mr. Loeb ———— own stock in ———. ——— markets ——— one of the competing products to Novartis' Exelon.

As a consultant Patient Representative advising the Peripheral and Central Nervous System Drugs Advisory Committee, Mr. Loeb potentially could become involved in matters that could affect his financial interest. Under 18 U.S.C. §208(a), he is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting Mr. Loeb to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Mr. Marshall Loeb that would permit him to participate in all official matters concerning supplemental new drug application (NDA) 20823, SE1-016, Exelon® (rivastigmine tartarte) Capsules (1.5 milligrams (mg), 3.0 mg, 4.5 mg, and 6.0 mg), sponsored by Novartis Pharmaceuticals Corporation, a subsidiary of Novartis AG, for the proposed indication of the treatment of mild to moderate dementia associated with Parkinson's disease.

First, Mr. Loeb's stock interest represents a minimal percentage of his ———— total net worth and is not so substantial as to preclude his participation in this matter.

Second, it is important to consider that Mr. Loeb's stock interest is in competing manufacturer, and not in the company whose product is coming before the committee for consideration. It is unlikely that the committee's recommendations regarding another product would have a direct and predictable impact on any of the competing products or companies. ——— is a large, diverse pharmaceutical firm that manufacture and distribute a large number of products. It does not depend on one or two products for its economic survival. Given the above considerations, I believe that the potential for a conflict of interest is minimal.

Moreover, Mr. Loeb is a ———————————— and the patient representative advising the committee. His participation is essential to providing the committee with input from the patient on medical and scientific issues. As the patient representative, Mr. Loeb's role is to represent the patient perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested patients, associations, coalitions, and patient organizations; and, facilitate dialogue with the advisory committee on scientific issues that affect patients.

Further, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the various advisory committee members. The Food and Drug Administration (FDA) is committed to expanding opportunities for patients to participate in FDA's decision making. The FDA invites Patient Representatives to participate in its Advisory Committee meetings to discuss medical products for the treatment of serious or life-threatening diseases, their experience as a patient enables Patient Representatives to bring a unique perspective to FDA Advisory Committee process. Mr. Loeb, _____ is a Columnist at MarketWatch.com. His role as the patient representative will bring an enormous amount of experience and knowledge that will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Mr. Marshall Loeb a waiver that will permit him to participate in all official matters regarding to discuss supplemental new drug application (NDA) 20823, SE1-016, Exelon® rivastigmine tartarte) Capsules (1.5 milligrams (mg), 3.0 mg, 4.5 mg, and 6.0 mg), sponsored by Novartis Pharmaceuticals Corporation, a subsidiary of Novartis AG, for the proposed indication of the treatment of mild to moderate dementia associated with Parkinson's disease. I believe that such a waiver is appropriate because in this case, the need for

Mr. Loeb's services outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: /s/ 4/10/06
Jenny Slaughter
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management
Date

DECISION:

X Waiver granted based on my determination, made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

_____ Waiver denied.

/s/ 4/11/06
Jason D. Brodsky
Acting Associate Commissioner
Office of External Relations
Food and Drug Administration
Date