MEMORANDUM

DATE: April 4, 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 Karl Kieburtz, M.D.

I am writing to request a waiver for Karl Kieburtz, M.D., a member of the Peripheral and Central Nervous System Drugs Advisory Committee, 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 Dr. Kieburtz 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 Dr. Kieburtz 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 has an arrangement concerning, prospective employment.

Dr. Kieburtz 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.

Dr. Kieburtz has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matter described previously. **Dr. Kieburtz is a member of ——— Steering Committee, and ——— Data Safety Monitoring Board for products unrelated to the product at issue, Exelon, and the competing products. ——— ——— is the sponsor of ——— and ——— ——— holds the license for ——— a competing product to Exelon®.**

As a member of the Peripheral and Central Nervous System Drugs Advisory Committee, Dr. Kieburtz 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 Dr. Kieburtz 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 Dr. Karl Kieburtz 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 and foremost, this waiver is justified because arguably, Dr. Kieburtz's interests do not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a), since his Steering Committee and Data Safety Monitoring Board are unrelated to the particular matter in which he is being asked to participate. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Kieburtz's financial interests are not so substantial as to preclude his participation in this matter. He receives no personal remuneration for these activities.

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 and Dr. Kieburtz's participation will contribute to the balance of views represented and the diversity of opinions and expertise. The Committee's intended purpose would be significantly impaired if the agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Kieburtz is Professor of Neurology and Community and Preventive Medicine and Director, Clinical Trials Coordination Center, Department of Neurology, at the University of Rochester School of Medicine and Dentistry. His primary clinical and research interests are in the treatment of neurodegenerative diseases affecting the basal ganglia, particularly Parkinson's disease, Huntington's disease, and HIV related neurological disorders. He has

been an active participant in the research activities of the Parkinson Study Group since 1989, and directs the Coordination Center for this and other multi-center academic consortia, including the Huntington Study Group. He is the principal investigator for the National Institutes of Neurological Disorders & Stroke sponsored trials of neuroprotective agents for Parkinson's disease. His publications and presentations have focused on experimental therapeutics and clinical research design strategies. I believe that Dr. Kieburtz's participation in the committee's discussions and deliberations will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Dr. Karl Kieburtz a waiver that will 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. I believe that such a waiver is appropriate because in this case, the need for Dr. Kieburtz'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