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 Sandra F. Olson, M.D.

I am writing to request a waiver for Sandra F. Olson, 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). The appointing official may grant waivers under 18 U.S.C. §208(b)(3) where "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. You are the appointing official for purposes of section 208; therefore, you have the authority to grant Dr. Olson a waiver under section 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. Olson is a special Government employee, she 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 her, her spouse, minor child, or general partner; an organization or entity for

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

Dr. Olson has been asked to participate in all official matters regarding supplemental New Drug Application (sNDA) 20823, SE1-016, Exelon (rivastigmine tartrate) Capsules (1.5 milligrams (mg), 3.0 mg, 4.5 mg, and 6.0 mg), sponsored by Novartis Pharmaceutical 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.

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 neurologic diseases and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Olson has advised the Food and Drug Administration (FDA) that she has financial interests that could potentially be affected by her participation in the matter described above. Dr. Olson owns stock in ——— and ——————. ——— markets ——— and ——— is distributed by ——————————— a subsidiary of ———————, these are two of the competing products to Novartis' Exelon.

As a member of the Peripheral and Central Nervous System Advisory Committee, Dr. Olson could potentially become involved in matters that could affect her financial interests. Under section 208, she 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. Olson 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. Olson that

would permit her to participate in the matter previously described.

First, Dr. Olson's stock interests represent a minimal percentage of her total net worth and are not so substantial as to preclude her participation in this matter.

Second, it is important to consider that Dr. Olson's stock interests are in competing manufacturers, 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. ——— and ——————— are large, diverse pharmaceutical firms that manufacture and distribute a large number of products. They do not depend on one or two products for their economic survival. Given the above considerations, I believe that the potential for a conflict of interest is minimal.

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. Olson'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. Sandra Olson is the Professor of Clinical Neurology at Feinberg Medical School of Northwestern University. She is board certified in Psychiatry and Neurology. Dr. Olson also serves as the President of the American Academy of Neurology (AAN), a position she assumed during the groups annual meeting in March 2003. The first woman to hold the office of the AAN president. Dr. Olson hopes during her term to expand the benefits of the organization's key programs in science, education, and member support, while emphasizing through lifelong learning, ethics, and patient care initiatives. She is active in many other organizations including the Accreditation Council for Graduate Medical Education, the American Medical Association Council on Medical Education,

the Illinois State Medical Society, and is a current board member of the State of Illinois' Department of Professional Regulation. Dr. Olson also serves on the board of governors of the Illinois State Medical Inter-Insurance Exchange Mutual Insurance Co. I believe that Dr. Olson's participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Sandra F. Olson, M.D., a waiver that will permit her to participate in all official matters regarding supplemental New Drug Application (sNDA) 20823, SE1-016, Exelon (rivastigmine tartrate) Capsules (1.5 milligrams (mg), 3.0 mg, 4.5 mg, and 6.0 mg), sponsored by Novartis Pharmaceutical 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 the services of Dr. Olson outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE:

/s/
Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

4/10/06
Date

DECISION:

__X__ Waiver granted based on my determination, made in accordance with section 18 U.S.C. §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/
Jason D. Brodsky
Acting Associate Commissioner
Office for External Relations
Food and Drug Administration

4/12/06
Date