DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: August 28, 2007

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vince Tolino
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: 208(b)(3) Conflict of Interest Waiver for Nelson Watts, M.D.

I am writing to request a waiver for Nelson Watts, M.D., a temporary voting member of the Cardiovascular and Renal 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 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. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Watts 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 his employer has a financial interest. Since Dr. Watts is a special Government employee, he is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

The function of the Cardiovascular and Renal Drugs Advisory Committee, as stated in its Charter, is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Watts has been asked to participate in all official matters concerning regulatory considerations for extending the use of phosphate binders from the dialysis population (where they are approved) to the pre-dialysis population (where no products are approved). The committee will hear presentations on this topic from Shire Development, Genzyme Corporation, and Fresenius Medical Care.

This matter is coming before a meeting of the Cardiovascular and Renal Drugs Advisory Committee. This issue is a particular matter involving specific parties.

Dr. Watts has advised the Food and Drug Administration (FDA) that he has a financial interest which could potentially be affected by his participation in the matter described above. Dr. Watts accepted an invitation to attend ——————— Advisors Meeting regarding an unrelated osteoporosis drug. According to Dr. Watts, he will receive minimal compensation for his participation in the meeting.———, a subsidiary of———, is an affected firm.

As a temporary voting member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. Watts potentially could become involved in matters that could affect his financial interest. Under section 208, 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. Watts 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. Watts that would allow him to participate fully in the matter described above because the need for his services greatly outweighs the conflict of interest created by this financial interest.

First, it is important to consider that Dr. Watts' interest in ——— is unrelated to the phosphate binders.

Second, Dr. Watts' financial interest in ——— is not so substantial as to preclude his participation in this meeting. He will receive minimal compensation for attending the Advisory Meeting.

Third, according to the review Division, the uniqueness of Dr. Watts' qualification justifies granting this waiver. Dr. Nelson Watts is a standing member and current chair for the Endocrinologic and Metabolic Drugs Advisory Committee. Dr. Watts has been asked to participate in this meeting due to his extensive expertise in the area of bone and mineral

disease. The topic of considerations for phosphate binder utilization in dialysis/pre-dialysis settings will likely include discussion of serum phosphorous levels in dialysis patients, and bone/mineral effects involved. Dr. Watts' participation will add the unique perspective needed in the area of bone and mineral disease, as well as osteoporosis. Dr. Watts has published extensively on variety of areas involving bone mineral density and osteoporosis. Dr. Watts is also currently involved in multiple clinical trials for the treatment of low bone mineral density in postmenopausal women, as well as other trials in osteoporosis and non-vertebral fractures. His participation in this meeting is essential to the topics being discussed because of the potential significant public health impact of the committee's recommendations.

Fourth, the difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies granting this waiver. In an attempt to gain the appropriate representation, the review Division considered 7 individuals listed as current SGEs with expertise in endocrinology. Of the seven endocrinologists, one declined due to a scheduling conflict and the rest were not contacted or pursued by the Division because their particular areas of expertise were not in bone and mineral diseases.

Moreover, 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 advisory committee. Also, 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 because of their demonstrated abilities.

Dr. Nelson Watts is Director of the University of Cincinnati Bone Health and Osteoporosis Center and Professor of Medicine, University of Cincinnati College of Medicine. He is board certified in Internal Medicine with subspecialty in endocrinology and metabolism, and board certified in bio-analysis and clinical densitometry. Dr. Watts is a member of numerous professional societies, such as the American Association of Clinical Endocrinologists, the American College of Physicians, the International Bone and Mineral Society, and the International Society for Clinical Densitometry. Dr. Watts has broad professional experience relating to endocrinology, and he has conducted extensive clinical research relating this field of study. I believe that participation by Dr. Watts in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee.

Accordingly, I recommend that you grant Nelson Watts, M.D., a waiver that would allow him to participate in all official matters concerning the regulatory considerations for extending the use of phosphate binders from the dialysis population (where they are approved) to the pre-dialysis population (where no products are approved). The committee will hear presentations on this topic from Shire Development, Genzyme Corporation, and Fresenius Medical Care. This issue is a particular matter involving specific parties. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Watts

outweighs the potential for a conflict of interest created by the financial interest attributed to him.

CONCURRENCE: /s/ 9/28/07

Vince Tolino
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/ 9/28/07

Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

Date