DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: August 28, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning
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 Nelson Watts, M.D.

I am writing to request a waiver for Nelson Watts, M.D., Chair of the Endocrinologic and Metabolic Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under section 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. 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 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. Watts 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. Watts has been asked to participate in all official matters concerning the committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products. Earlier this year, FDA requested that manufacturers of currently marketed levothyroxine sodium products provide to it certain product release and stability information. The committees' will consider FDA's analyses and any clinical significance. This issue is coming before a joint meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Science.

The function of the Endocrinologic and Metabolic Drugs Advisory Committee 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 endocrine and metabolic disorders and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Watts has advised the Food and Drug Administration that he has a financial interest that could potentially be affected by his participation in the matter at issue. **Dr. Watts is a consultant to ——— on osteoporosis. Dr. Watts receives minimal compensation for his participation. ——— , is distributed by ——— , a subsidiary of ——— .**

As a member of the Endocrinologic and Metabolic Drugs Advisory Committee, Dr. Watts 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. 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, which would permit him to participate in the matter described above.

First, Dr. Watts' interest is not so substantial as to preclude his participation in this matter. He receives minimal compensation.

Second, arguably, his interest does not constitute a financial interest in the matter within the meaning of 18 U.S.C §208(a), since his interest in [redacted] is unrelated to the issue coming before the committees, and the affected products.

Third, this waiver is also justified, in part, because of the nature of matters to be discussed. The committees' discussion of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products, will not have a unique and distinct impact on any particular levothyroxine product, or firm. Rather, the discussions could affect all currently marketed levothyroxine products and their manufacturers. This poses far less of a conflict than participation in matters that relate specifically to a particular firm in which Dr. Watts has an interest.

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 advisory committee. Also, the committees' 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. He has written extensively on topics concerning post-menopausal osteoporosis, the impact of hip fractures and hip surgery in elderly men and women, and the modern solutions to common endocrinologic problems, such as disorders of glucose metabolism. Dr. Watts has broad professional experience relating to endocrinology, and he has conducted extensive clinical research relating this field of study. I believe his participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Nelson Watts, M.D., a waiver that will permit him to participate in all official matters concerning the committees' discussions of FDA's efforts to assess the product quality of currently marketed levothyroxine sodium drug products. Earlier this year, FDA requested that manufacturers of currently marketed levothyroxine sodium products provide to it certain product release and stability information. The joint committee will consider FDA's analyses and any clinical significance. I believe that such a waiver is appropriate because in this case, the need for the services of Nelson Watts, M.D., outweighs the potential for a

conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /S/ 9/13/06

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

Date

DECISION:

✓ 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/ 9/14/06

Randall Lutter, Ph.D.
Associate Commissioner for Policy
and Planning
Food and Drug Administration

Date