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 Michael McClung, M.D.

I am writing to request a waiver for Michael McClung, M.D., a consultant to the Center for Drug Evaluation and Research, 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. McClung 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. McClung 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. McClung 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 & Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Science.

The committees' function statements as stated in their Charters are as follows: 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. The Pharmaceutical Science Advisory Committee is to provide advice on scientific and technical issues concerning the safety, and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases, and as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities. The committees make their appropriate recommendations to the Commissioner of Food and Drugs.

Dr. McClung 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. McClung is a member of ———— Global Advisory Board for ————————, a product unrelated to that coming before the committees' for consideration. Dr. McClung receives minimal compensation for his participation. ———————————— ———, is distributed by———, a subsidiary of ————————.**

As a consultant advising the committees, Dr. McClung 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. McClung 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. McClung, which would permit him to participate in the matter described above.

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

Second, Dr. McClung's interest in _____ is unrelated to the issues to be discussed and the affected products. Arguably, his interest does not constitute a financial interest in the matter under 18 U.S.C. § 208(a). Nevertheless, in the utmost of caution, I recommend that this wavier be granted.

Third, this waiver is also justified, in part, because of the nature of the issues to be discussed. The committees' discussions 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 Dr. McClung's financial interest, but rather may affect all levothyroxine products and their manufacturers. While this participation may be covered by section 208, it poses far less risk of a conflict.

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. In addition, 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. Michael McClung is the Director of the Oregon Osteoporosis Center. He also serves as Assistant Director of Medical Education at Portland Providence Medical Center, and is Associate Professor of Medicine at Oregon Health and Science University. He is board certified in internal medicine with a subspecialty in endocrinology and metabolism, and he has a special interest in disorders of skeletal and mineral metabolism. Dr. McClung is a member of numerous professional societies, such as, the Endocrine Society, the American Society for Bone and Mineral Research, the International Society for Clinical Densitometry, the American Association of Clinical Endocrinologists, Medical Advisory Board, and the Scientific-Educational Advisory Committee. He also serves on the Editorial board for Osteoporosis Today, North American Menopause Society, and the Journal of Clinical Densitometry. I believe his participation will contribute to the diversity of opinions and expertise represented on at this meeting and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Michael McClung, 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 Michael McClung, 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