DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: December 20, 2005

TO: Sheila Dearybury Walcoff, Esq.
Associate Commissioner for 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.
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

SUBJECT: Conflict of Interest Waiver for Margaret E. Wierman, M.D.

I am writing to request a waiver for Margaret E. Wierman, M.D., a member of the Endocrinologic and Metabolic 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. Wierman 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. Wierman 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 as an arrangement concerning, prospective employment.

Dr. Wierman has been asked to participate in all official matters concerning consideration of the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules, sponsored by GlaxoSmithKline Consumer Healthcare, L.P., an associate of GlaxoSmithKline PLC, to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet. This matter is coming before the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee for consideration.

The function of the Nonprescription Drugs Advisory Committee is to review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee also serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof.

The function of the Endocrinologic and Metabolic Drugs Advisory Committee is to review and evaluate 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. Wierman has advised the Food and Drug Administration that she has financial interests that could potentially be affected by her participation in the matter

previously described. Dr. Wierman is a member of Speaker's Bureaus for [redacted] and [redacted] that have investigational agents under study for use in the treatment of obesity. Dr. Wierman lectures on topics unrelated to Orlistat and its competing products, and she receives nominal compensation from each firm.

As a member of the Endocrinologic and Metabolic Drugs Advisory Committee, Dr. Wierman potentially could become involved in matters that could affect her financial interests. Under 18 U.S.C. §208(a), 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. Wierman 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. Wierman that would permit her to participate all official matters concerning consideration of the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules, sponsored by GlaxoSmithKline Consumer Healthcare, L.P., an associate of GlaxoSmithKline PLC, to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet.

First and foremost, this waiver is justified because arguably, Dr. Weierman's interests do not constitute financial interests in the particular matter within the meaning of 18 U.S.C. §208(a), since she lectures on topics unrelated to Orlistat and its competing products. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Wierman's financial interests are not so substantial as to preclude her participation in this matter. She receives modest compensation for serving on the Speaker's Bureaus.

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. Wierman's participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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 as a result of their demonstrated abilities. Margaret E. Wierman, M.D., is currently Chief of Endocrinology at the Denver Veterans Affairs Medical Center and Professor of Medicine, Physiology and Biophysics, at the University of Colorado School of Medicine. Her clinical interests are in reproductive endocrinology and neuroendocrinology. Her basic research interests are in the control of Gonadotropin releasing hormone (GnRH) gene expression to better understand what turns on and off the reproductive axis. Dr. Wierman's current research projects focus on the mechanisms of transcriptional repression by liganded steroid receptors, the role of homeobox transcription factors in the developmental control of GnRH and the identification of novel factors that control GnRH neuronal migration and gene expression. Her recent leadership activities include: President of Women in Endocrinology, President of the Western Section of Clinical Investigation, Chair of the Meetings and Educational Programs for The Endocrine Society and Councilor, The Endocrine Society. She is a member of numerous professional societies, such as the American Federal of Clinical Research, Women in Endocrinology, the American Society of Clinical Investigation, and The Endocrine Society. I believe that Dr. Wierman's participation in the committees' 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. Margaret E. Wierman a waiver that will permit her to participate in all official matters concerning consideration of the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules, sponsored by GlaxoSmithKline Consumer Healthcare, L.P., an associate of GlaxoSmithKline PLC, to promote weight loss in

overweight adults when used along with a reduced calorie and low fat diet. I believe that such a waiver is appropriate because in this case, the need for Dr. Wierman's services outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE: _____ 12/28/05
Jenny Slaughter Date
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management

DECISION:

✓ 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.

_____ 12/29/05
Sheila Dearybury Walcoff, Esq. Date
Associate Commissioner for External Relations
Food and Drug Administration