DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

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 Marie Griffin, M.D.

I am writing to request a waiver for Marie Griffin, 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 Therefore, you have the authority to grant Dr. Griffin 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. Griffin 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

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negotiating for, or as an arrangement concerning, prospective employment.

Dr. Griffin has been asked to participate in the joint Nonprescription Drugs Advisory Committee and Endocrinologic and Metabolic Drugs Advisory Committee meeting to consider 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.

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. Griffin has advised the Food and Drug Administration (FDA) that her and her employer, the Vanderbilt University Medical Center, have a financial interest that could potentially be affected by her participation in the matter described above. Dr. Griffin is

chair of [redacted] that have investigational products under study that could compete with Orlistat. Dr. Griffin does not receive direct compensation for serving as chair. Rather, the compensation is paid to the Department of Preventative Medicine where she is a faculty member. Currently the funds are being used in support of a post-doctoral fellow.

As a consultant advising the Nonprescription Drugs Advisory Committee and Endocrinologic and Metabolic Drugs Advisory Committee, Dr. Griffin potentially could become involved in matters that could affect her and her employer's financial interest. 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. Griffin 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. Griffin that would permit her to participate in the matters previously described.

First and foremost, this waiver is justified because arguably, Dr. Griffin's and her employer's interest does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a). The committee which Dr. Griffin chairs advises on products and issues unrelated to Orlistat and its competing products. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Moreover, Dr. Griffin and her employer's financial interest is not so substantial as to preclude her participation in this matter. The compensation that Vanderbilt receives for Dr. Griffin's work on the monitoring committee is not substantial in relation to the Departments total budget.

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. Griffin'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. Marie Griffin, M.D., is Professor of Preventive Medicine, Professor of Medicine, and primary faculty member, Department of Preventive Medicine, Vanderbilt University Medical Center. Dr. Griffin's research focuses on pharmacoepidemiology, health services research, infectious diseases and vaccines. She has written numerous publications on such topics as post-marketing surveillance for drug safety, evaluating drugs after their approval for use, and variations in morbid obesity and bariatric surgery use. I believe that Dr. Griffin's expertise in epidemiology and drug safety is essential for evaluating the safety and efficacy of Orlistat as an over-the-counter product. Dr. Griffin's participation will contribute to the diversity of expertise and viewpoints represented at this meeting.

Accordingly, I recommend that you grant Marie Griffin, M.D., 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 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 the services of Dr. Griffin outweighs the

potential for a conflict of interest created by the financial interest attributable to her.

CONCURRENCE: _____ 12/27/05
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 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.

_____ 12/30/05
Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration
Date