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 Ruth M. Parker, M.D.

I am writing to request a waiver for Ruth M. Parker, M.D., a member of the Nonprescription 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. Parker 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. Parker 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. Parker 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. Parker has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the matter

previously described. Dr. Parker is one of the co-editors of a special issue of the *Journal of General Internal Medicine* on health literacy. [redacted] is studying an investigational product that could potentially compete with Orlistat is providing an unrestricted educational grant to the *Journal of General Internal Medicine* in support of this special issue. Dr. Parker will receive nominal compensation from the journal for her work as co-editor.

As a member of the Nonprescription Drugs Advisory Committee, Dr. Parker potentially could become involved in matters that could affect her 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. Parker 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. Parker 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 use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules 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. Parker's interest does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. §208(a), since her interest is unrelated to Orlistat and the competing products. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Parker's financial interest is not so substantial as to preclude her participation in this matter. She will receive nominal compensation for her work as co-editor.

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. Parker'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. Ruth M. Parker, M.D., is Professor of Medicine and Associate Director of Faculty Development for the Division of General Medicine at the Emory University School of Medicine. Dr. Parker's primary research interests and activities are in the area of medical education and health services of under-served populations. Over the past 10 years, Dr. Parker has focused exclusively on the healthcare issues of under-served populations, particularly health literacy. She was a principal investigator in the Robert Wood Johnson Literacy in Health Study and helped create a measurement tool to quantify patients' ability to read and understand health information. She has written numerous papers on health literacy, and co-edited the complete bibliography of medicine on health literacy for the National Library of Medicine. She is currently chair of the steering committee for the American Medical Association Foundation's national signature program on health literacy, and is a member of the Institute of Medicine's Committee on Health Literacy. Dr. Parker is a member of various professional societies, such as the American College of Physicians, Society of General Internal Medicine, American Public Health Association, and the American Medical Association. Factors taken into consideration in determining whether a prescription drug should be made available over-the-counter is whether consumers can self-diagnose the illness, comprehend the label and understand the warnings, and use the product without medical supervision. Dr. Parker's expertise in health literacy is essential for the discussions of whether Orlistat should be made available without a prescription.

Accordingly, I recommend that you grant Dr. Ruth M. Parker 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. Parker's services outweighs the potential for a conflict of interest created by the financial interest attributable to her.

CONCURRENCE: _____ 12/28/05

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.

_____ 12/29/05

Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

Date