DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: December 4, 2006

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

THROUGH: Vince Tolino
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 Melissa Gilliam, M.D., M.P.H.

I am writing to request a waiver for Melissa Gilliam, M.D., M.P.H., serving on the Advisory Committee for Reproductive Health Drugs as a consultant, 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. Gilliam, 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 her employer has a financial interest. Since Dr. Gilliam is a special Government employee, she is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to her or her employer.

Dr. Gilliam has been asked to participate in the discussions of the current issues that influence the consideration for approval of oral and non-oral (i.e., transdermal and intravaginal) hormonal contraceptive drug products. Issues for discussion will include clinical trial design, expectations for efficacy and safety outcomes, and measures of acceptability of the product to the user, including cycle control. These matters are coming before the Advisory Committee for Reproductive Health Drugs for consideration and are particular matters of general applicability.

The function of the Committee, as stated in its Charter, is to review and evaluate data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Gilliam has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the matter to be discussed.

Dr. Gilliam attended ———— sponsored train the trainer program on ————. She received minimal compensation for her participation. Dr. Gilliam has agreed to train other physicians in how to properly insert ————. In the future, she will receive a modest fee for the individuals she trains on the implantation of ————. She has not performed any training to date.

As a consultant advising the Advisory Committee for Reproductive Health Drugs, Dr. Gilliam 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. Gilliam 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. Gilliam allowing her to participate in the matters previously described.

First, the issues to be addressed by the Committee are a particular matter of general applicability, involving an entire class of products and granting no advantage to any particular individual firm. Therefore, the Committee's recommendations would not be expected to have a significant financial impact on any specific firm and the potential of bias on the part of Dr. Gilliam should be mitigated.

Second, given the nature of Dr. Gilliam's unrelated consulting arrangement, there is little likelihood that the Committee's recommendations will affect the viability of ——— or her ongoing relationship with them. Therefore, the potential concern that Dr. Gilliam's impartiality might be called into question during the Committee's deliberations should be diminished.

Third, the Committee's role is advisory in nature. The Agency officials making the decisions are not bound by the recommendations of the Committee and will take into consideration Dr. Gilliam's interest when making a final decision.

Moreover, the amount of compensation is not so substantial as to preclude her participation in this meeting.

Lastly, 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 committee. Also, the Committee's 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. Dr. Gilliam is Associate Professor of Obstetrics and Gynecology

at the University of Chicago. She is also Chief of the Division of Family Planning and Contraceptive Research in the Department of Obstetrics and Gynecology at the University of Chicago and Director of the Fellowship in Family Planning. With degrees in English literature, philosophy and politics, Dr. Gilliam's research takes a broad approach to the study of family planning. She employs social science, qualitative and quantitative techniques to explore contraceptive behaviors. Also, Dr. Gilliam has a clinical interest in pediatric and adolescent gynecology. Dr. Gilliam will bring a unique research experience and literature contribution in the areas of contraceptive use and compliance among minorities, specifically African American Women and latina women and adolescents. Dr. Gilliam's unique perspective is essential for a discussion of the differences in findings from trials conducted in countries whose populations are primarily Caucasian, and translation to the use of these products in the United States, which has a very diverse population with large African American and Hispanic components.

Accordingly, I recommend that you grant Melissa Gilliam, M.D., M.P.H., a waiver that will permit her to participate fully in all official matters before the Committee related to the discussions of current issues that influence the consideration for approval of oral and non-oral (i.e., transdermal and intravaginal) hormonal contraceptive drug products. Issues for discussion will include clinical trial design, expectations for efficacy and safety outcomes, and measures of acceptability of the product to the user, including cycle control. I believe that such a waiver is appropriate because in this case, the

need for the services of Dr. Gilliam outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: _____/s/_____ 12|14|06
Vince Tolino Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

___X___ 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/_____ 12|22|06
Randall Lutter, Ph.D. Date
Associate Commissioner for
Policy and Planning