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 Marvin Meyer, Ph.D.

I am writing to request a waiver for Marvin Meyer, Ph.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. Meyer 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. Meyer 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. Meyer 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. Meyer 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. Meyer serves as a consultant to ——— on issues unrelated to that coming before the committees' for consideration. Dr. Meyer receives moderate compensation for his participation. ——————— is manufactured by ——————— , a subsidiary of ———.**

APPEARS THIS WAY
ON ORIGINAL

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

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

Second, Dr. Meyer's interest in ——— is unrelated to the issues coming before the committee, and the affected products. Arguably, his interest does not constitute a financial interest in the particular matter within the meaning of 18 U.S.C. 208(a). Nevertheless, in an abundance of caution, I recommend that this wavier be granted.

Third, this waiver is also justified, in part, because of the nature of the matters 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 any one levothyroxine product or manufacturer. Rather, all manufacturers and their products may be affected to the same extent. While this participation may be covered by section 208, it poses far less risk of a conflict than participation in matters that relate specifically to a firm in which Dr. Meyer has an interest.

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. Marvin Meyer is Emeritus Professor, former Chairman of the Department of Pharmaceutical Sciences and Associate Dean for Research and Graduate Programs at the College of Pharmacy, University of Tennessee. He has published over 110 publications in the areas of bioavailability, pharmacokinetics and assay methodology. Dr. Meyer is a member of numerous professional societies, such as, the American Pharmaceutical Association, the American Association of College of Pharmacy, Academy of Pharmaceutical Sciences, and the American Association of Pharmaceutical Sciences. I believe his participation will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Marvin Meyer, Ph.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 Marvin Meyer, Ph.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