



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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DATE: June 4, 2008

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vince Tolino /s/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

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Michael F. Ortwerth, Ph.D. /s/
Deputy Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Igor Cerny, Pharm.D. /s/
Director, Advisors and Consultants Staff
Center for Drug Evaluation and Research

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SUBJECT: 712(c)(2)(B) Conflict of Interest Waiver for Marvin Meyer, Ph.D.

I am writing to request a waiver for Dr. Marvin Meyer, a temporary voting member of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, from the conflict of interest prohibitions of section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Dr. Meyer a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. Because Dr. Meyer is a special Government employee, he 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 him.

The function of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology 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, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities.

Dr. Marvin Meyer has been asked to participate in the July 22-23, 2008, meeting on (1) the current thinking on issues pertaining to the use of nanotechnology in drug manufacturing, drug delivery, or drug products; (2) current strategies and directions for the testing of lead in pharmaceutical products; (3) the bioequivalence methods for locally acting drugs that treat gastrointestinal (GI) conditions; (4) the use of inhaled corticosteroids dose-response as a means to establish bioequivalence of inhalation drug products; and, (5) the drug classification of orally disintegrating tablets (ODT) as a separate dosage form and the need for subsequent guidance on expectations and recommendations that would be required for applications proposing the dosage form.

These matters are coming before the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology. These issues are particular matters of general applicability. The discussions will not have a distinct impact on any particular product or firm. Rather, the discussions could affect all products and firms to the same extent.

Dr. Marvin Meyer has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. Marvin Meyer owns stock in two health care sector mutual funds.

As a temporary member to the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, Dr. Meyer could become involved in matters that could affect his financial interests. Under section 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. Meyer to participate in such matters if necessary to afford this committee essential expertise.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Meyer that would allow him to participate fully in the matter described because his voting participation is necessary to afford the committee essential expertise.

First, Dr. Meyer's interests in the sector mutual funds are not so substantial as to preclude his participation in the meeting. Dr. Meyer owns a moderate number of shares.

Second, the issues to be discussed by the committee are particular matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the committee recommendations would not be expected to have a significant financial impact on any specific firm and the potential perception of bias on the part of Dr. Meyer should be mitigated.

Third, the uniqueness Dr. Meyer's qualification justifies granting this waiver. Dr. Marvin Meyer, a prior member of the Advisory Committee for Pharmaceutical Science (ACPS), has a long, distinguished, and recognized career in the pharmaceutical sciences field. He is the former Chairman of the Department of Pharmaceutical Sciences and the Department of Pharmaceutics at the University of Tennessee. He has held numerous ancillary appointments over the years, to include activities at many pharmaceutical companies, expert committees (governmental and industrial), expert peer review, and professional societies. His recognized achievements (honors) and experience have provided Dr. Meyer a very unique set of tools and qualifications within the pharmaceutical community. Such diversity of experience made him an exceptional participant in advisory committee activities during his tenure on the ACPS.

While the issues coming before the committee are very broad in nature and diverse, they are indicative of the Office of Pharmaceutical Science focus to advancing cutting edge science into the overall direction of Agency activities. It is imperative for the Agency to stay abreast of advances in pharmaceutical manufacturing processes and to ensure that regulatory requirements and policy are reflective of state-of-the-art thinking. Accordingly, since the range of topics at any one meeting is typically varied and broad in their scope, it is almost a necessity for pharmaceutical science advisory committee membership to have members that are multi-discipline and with experience that touches on a wide range of applicable fields. However, the typical general nature of the topics makes it difficult to having such membership without multiple waivers necessary for meeting participation. Very few of the current membership possess such diversity in disciplines.

Fourth, the difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies granting this waiver. Locating qualified individuals without disqualifying financial interest to serve on this advisory committee has been very difficult, even after screening all committee members and numerous special Government employees (SGEs). It is imperative that the committee have a sufficient number of members with an expertise in appropriate disciplines in order to have a meaningful discussion of these topics. In anticipation of potential screening issues, three additional SGEs were considered for attending this meeting. One of these SGEs has already been recused. Because of the general nature of the topics, other committee members have also been conflicted in one way or another, restricting appropriate available membership for discussion of some of the topics. Additionally, the remaining current committee membership has a large component of new members with no prior experience on advisory committees. The new members have very focused backgrounds. Accordingly, leadership for committee discussions is very necessary. Dr. Meyer, an SGE with prior membership experience with ACPS, has the required diverse background that is of importance in discussions of the varied topics presented by the agenda. Dr. Meyer, as mentioned above, has an extensive background in the pharmaceutical sciences and regulatory processes, to include pharmaceutical technology, biopharmaceutics, advanced pharmacokinetics, bioavailability, pharmaceutical analysis, pharmaceutical manufacturing concepts, and regulatory processes. He has been instrumental in developing and teaching graduate/undergraduate courses in regulatory affairs and compliance issues, covering drugs, biologics and devices to provide scientific and regulatory specifics on product approval and post marketing activities. Additionally, he has served as a consultant to various academic institutes in the areas of product development, pharmacokinetics, regulatory affairs, quality and compliance. His demonstrated leadership in discussions will be instrumental to a successful vetting of the agenda topics. The review division

feels strongly that Dr. Meyer has the background and expertise to lead appropriate and stimulating discussions during the meeting. His demonstrated experience of various disciplines relevant to the general fields of knowledge surrounding the topics brings a wide range of knowledge to this meeting that is not held by other members.

Moreover, 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. 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. I believe that Dr. Meyer's participation in the committee's deliberations will contribute to the diversity of opinions and expertise represented on the committee. Accordingly, I recommend that you grant Dr. Meyer a waiver that would allow him to participate in all official matters concerning (1) the current thinking on issues pertaining to the use of nanotechnology in drug manufacturing, drug delivery, or drug products; (2) current strategies and directions for the testing of lead in pharmaceutical products; (3) the bioequivalence methods for locally acting drugs that treat gastrointestinal (GI) conditions; (4) the use of inhaled corticosteroids dose-response as a means to establish bioequivalence of inhalation drug products; and, (5) the drug classification of orally disintegrating tablets (ODT) as a separate dosage form and the need for subsequent guidance on expectations and recommendations that would be required for applications proposing the dosage form. I believe that such a waiver is appropriate because in this case, Dr. Meyer's voting participation is necessary to afford the committee essential expertise.

DECISION:

~~X~~ Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the committee essential expertise. Formatted: Underline

_____ Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the committee essential expertise.

_____ Waiver denied.

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Randall W. Lutter, Ph.D. Date 6/30/08 Formatted: Underline
Deputy Commissioner for Policy Deleted: _
Food and Drug Administration Formatted: Underline