DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration

Rockville MD 20857

DATE: February 20, 2007

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

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 Dennis Turk, Ph.D.

I am writing to request a waiver for Dennis Turk, Ph.D., a member of the Arthritis Drugs Advisory Committee, 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. Turk 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. Turk 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. Turk has been asked to participate in all official matters concerning the safety and efficacy of New Drug Application (NDA) 21-389/21-772, proposed trade name, Arcoxia (etoricoxib), a non-steroidal, anti-inflammatory, cyclooxgenase-2 (COX-2) enzyme inhibitor, manufactured by Merck & Company, Inc., for the proposed indication of the relief of the signs and symptoms of osteoarthritis. This matter is a particular matter involving specific parties.

The function of the Arthritis Advisory Committee, as stated in its Charter, 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 arthritis, rheumatism, and related diseases, and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Turk 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. Turk serves on an unrelated advisory board for ———. ——— manufactures two of the many competing products to Arcoxia.**

As a member of the Arthritis Drugs Advisory Committee, Dr. Turk 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. Turk 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. Turk that would permit him to participate in the matter previously described.

**First, Dr. Turk's interest in ——— is not so substantial as to preclude his participation in this matter. He receives minimal compensation for his advisory board activities.**

Second, the uniqueness of Dr. Turk's qualifications justifies granting this waiver. Dr. Turk is a nationally recognized leader in the research and treatment of pain and the only committee member with this particular expertise. Dr. Turk's extensive knowledge and experience in the design and conduct of clinical trials specific to pain will contribute

greatly to the committee's understanding and evaluations of Arcoxia's clinical studies.

Dr. Turk's participation in the meeting is also critical because he has been chosen to chair the meeting. The Division feels strongly that Dr. Turk has the background and expertise to lead an appropriate and stimulating discussion during the committee meeting.

Moreover, the difficulty of locating a similarly qualified individual without a disqualifying financial interest to serve on the committee also justifies granting this waiver. It has been exceedingly difficult to find qualified pain specialist with the requisite experience in the research and treatment of pain who have not had any involvement with the product, competing products, or the affected firms. The Division searched and polled a number of current special Government employees and Federal employees at the National Institutes of Health (NIH) for their availability. The search yielded no individual with comparable experience and the Division was unable to find anyone as qualified as Dr. Turk who was available to participate. Therefore, we request to use the services of Dr. Turk. who will serve as the only pain specialist on the panel. The Division feels that the absence of a pain specialist on the committee will limit the discussion and may call into question the validity of any committee recommendations to the Agency.

Finally, 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. Dr. Dennis Turk is a professor of anesthesiology and Pain Research and Director of the Fibromyalgia Research Center at the University of Washington, School of Medicine in Seattle. As a recent president of the American Pain Society and as a Co-facilitator of the Initiatives on Methods Measurement and Pain Assessment in Clinical Trials, Dr. Turk is at the forefront of developments in clinical pain research and clinical trial design. He has presented numerous educational courses and workshops on the subjects of Assessment and Treatment of Chronic Pain, and Cognitive-Behavioral Therapy of Chronic Pain, and has published extensively in numerous book chapters, journals,

abstracts in these areas. Dr. Turk is a member of numerous professional societies, such as the American Psychological Association, the Academy of Behavioral Medicine Research, the American Pain Society, and Fellow, the Society of Behavioral Medicine. 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.

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Accordingly, I recommend that you grant Dennis Turk, Ph.D., a waiver that will permit him to participate in all official matters concerning the safety and efficacy of New Drug Application NDA 21-389/21-772, proposed trade name, Arcoxia (etoricoxib), a non-steroidal, anti-inflammatory, cyclooxgenase-2 enzyme (COX-2) inhibitor, manufactured by Merck & Company, Inc., for the proposed indication of the relief of the signs and symptoms of osteoarthritis. I believe that such a waiver is appropriate because in this case, the need for the services of

Dr. Dennis Turk outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE: /s/ 2/28/07

Vince Tolino
Director, Ethics and
Integrity Staff
Office of Management Programs
Office of Management

Date

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/ 3/6/07

Randall W. Lutter, Ph.D.
Associate Commissioner for Policy
and Planning
Food and Drug Administration

Date