DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: November 8, 2006

TO: Randall 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 Louis Morris, Ph.D.

I am writing to request a waiver for Louis Morris, Ph.D., a member of the Drug Safety and Risk Management 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. Morris 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. Morris 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. Morris has been asked to participate in all official matters concerning the safety and efficacy of New Drug Application NDA 20-998, supplement 021, trade name, Celebrex (celecoxib), a non-steroidal anti-inflammatory drug (COX-2 inhibitor), manufactured by Searle Ltd. for G.D. Searle LLC, subsidiaries of Pfizer, for the proposed indication of the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients two years and older. This matter is coming before the Arthritis Advisory Committee and 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. Morris has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matter at issue. **Dr. Morris serves as a consultant to ——— on activities unrelated to the matter coming before the committee or the competing products. Dr. Morris receives minimal compensation for his participation. Dr. Morris also has an ongoing consulting relationship with ———————. Dr. Morris has no consulting currently scheduled, he receives minimal compensation annually. Dr. Morris has also reported that he serves as an expert witness for ———————, a law firm, who represents ——— regarding two unrelated products. Dr. Morris receives moderate compensation from ———————. ———, a competing product to Celebrex, is manufactured by ——————————————————————————— ——————————; ——————————— ———————————, a subsidiary of ——————————— ——————————; and, ———— by ——— ————. ——————————— is the manufacturer of ———, and ——————————— is the manufacturer of ——— —. ——————————— and ——————————— are subsidiaries of ———.**

As a member of the Drug Safety and Risk Management Advisory Committee advising the Arthritis Drugs Advisory Committee, Dr. Morris potentially could become involved in matters that could affect his financial interests. 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. Morris 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. Morris, which would permit him to participate in the matter described above.

First, Dr. Morris' interests are unrelated to the product coming before the committee, or the competing products.

Second, the uniqueness of Dr. Morris' qualification justifies granting this waiver. Dr. Louis Morris has extensive experience on risk assessment, risk management and the communication of the risks and therapeutic benefits of pharmaceutical products. He has published extensively on product labeling, patient package inserts, physician and patient education, as well as on drug marketing and promotion. He would have extremely valuable insights for the discussions that will occur with respect to Celebrex and juvenile rheumatoid arthritis (JRA). Dr. Morris is currently a member of the Drug Safety and Risk Management Advisory Committee and has made important contributions to their deliberations on a variety of safety issues that have come before that committee. He attended the Advisory Committee meeting held in February 2005 on Vioxx, other COX-2 inhibitors and NSAIDs, and is therefore particularly uniquely qualified to understand the complex issues associated with this class of drugs, their risk assessment and how to communicate these risks.

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 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. Dr. Morris is President of Louis A. Morris and Associates, Inc. In this position, Dr. Morris provides research, consulting, training and project development services. He works on a variety of issues including patient information and compliance, prescription to over-the-counter switches, advertising regulation, risk management, health policy, and communications research. Prior to his current position, Dr. Morris served as Senior VP at SCP Communications. He also served at the Food and Drug Administration for 23 years, where he held a variety of positions including Acting Division Director and Branch Chief in the Division of Drug Marketing, Advertising and Communications. Dr. Morris has also served as a Scholar-in-Residence at the American University's Department of Marketing as well as on the faculty at Johns Hopkins University, University of Maryland, George Washington University, and Georgetown University Medical School. He has authored over 100 journal articles and book chapters on the topics of health and risk communications. Dr. Morris has served as an expert consultant to the Federal Trade Commission, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Harvard University's Center for Risk Analysis, and numerous pharmaceutical and communication companies. He serves on the editorial board of several pharmaceutical and marketing journals. Dr. Morris earned his doctoral degree in psychology from Tulane University. He served as president of the Drug Information Association from 1994-1995 and was a chair of the Health Policy Committee of the International Society of Pharmacoeconomics and Outcomes Research. 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 Louis Morris, Ph.D., a waiver that will permit him to participate in all official matters concerning the safety and efficacy of New Drug Application NDA 20-998, supplement 021, trade name, Celebrex (celecoxib), a non-steroidal anti-inflammatory drug (COX-2

inhibitor), manufactured by Searle Ltd. for G.D. Searle LLC, subsidiaries of Pfizer, for the proposed indication of the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients two years and older. I believe that such a waiver is appropriate because in this case, the need for the services of Louis Morris, Ph.D., outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: /s/ 11/8/06

Vince Tolino
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 thepotential for a conflict of interest created by the financial interest attributable to the individual.

_____ Waiver denied.

/s/ 11/8/06

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

Date