DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: October 20, 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 Joan M. Bathon, M.D.

I am writing to request a waiver for Joan M. Bathon, M.D., a member of the Arthritis Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). The appointing official may grant waivers under 18 U.S.C. §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. You are the appointing official for purposes of section 208; therefore, you have the authority to grant Dr.Bathon a waiver under section 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. Since Dr. Bathon is a special Government employee, she 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 her, her spouse,

minor child, or general partner; an organization or entity for which she serves as an officer, director, trustee, general partner, or employee; and, a person with whom she is negotiating for, or has an arrangement concerning, prospective employment.

Dr. Bathon has been asked to participate in all official matters regarding 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 issue is a particular matter involving specific parties.

The function of the Arthritis 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 arthritis, rheumatism, and related diseases, and to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Joan M. Bathon has advised the Food and Drug Administration that she has a financial interest that could potentially be affected by her participation in the matter at issue. **Dr. Bathon is a consultant to ——— regarding novel drugs under study for the treatment of rheumatoid arthritis. She has not discussed COX-2 drugs or NSAIDS. According to Dr. Bathon, her consulting is unrelated to the matter coming before the committee or the competing products. ——— makes ——————— and ———, competing products to Celebrex.**

As a member advising the Arthritis Drugs Advisory Committee, Dr. Bathon could potentially become involved in matters that could affect her financial interest. Under section 208, 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. Bathon 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 Joan Bathon, M.D., that would permit her to participate in the matter previously described.

First, Dr. Bathon's interest is not so substantial as to preclude her participation in this matter. She receives minimal compensation for consulting.

Second, the uniqueness of Dr. Bathon's qualification justifies granting this waiver. Dr. Bathon is a standing member of the Arthritis Advisory Committee. She has attended previous meetings on products indicated for the treatment on pain from rheumatoid arthritis to include the FDA Advisory Committee meeting held February 16-18, 2005 held to discuss the cardiovascular risk posed by painkillers known as Cox-2 inhibitors, which included Celebrex, Bextra and Vioxx. Her expertise in the area of anti-inflammtory diseases will provide a analytical and clinical expertise needed to evaluate the product at issue for its indication. Dr. Bathon has made a significant commitment to the integration of behavioral/social science to the understanding of pain and its relief in patients with arthritis. Her a well-rounded knowledge and complete understanding of pain and the limitations pain from arthritis creates for pain patients, provides a knowledge base that is relevant to the issues associated with the celebrex.

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 various advisory committee members and Dr. Bathon's participation will contribute to the balance of views represented and the diversity of opinions and expertise. 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. Bathon is Professor of Medicine, and Co-Director of the Division of Rheumatology, Department of Medicine at Johns Hopkins University, and Director of Johns Hopkins Arthritis Center, Johns Hopkins Bayview Medical Center. Dr. Bathon's research focuses on the mechanisms of inflammation and joint destruction as they relate to rheumatoid arthritis (RA) and osteoarthritis (OA). Her clinical interests include therapeutic agents for the treatment of RA and OA, evaluation of cartilage and bone epitopes as markers of OA in aging women, and exercise/weight management for osteoarthritis. I believe that Dr. Bathon's participation will contribute to the diversity of expertise and viewpoints represented and will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Joan M. Bathon, M.D., a waiver that will permit her to participate in all official matters concerning regarding 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 Dr. Joan Bathon outweighs the potential for a conflict of interest created by the financial interest attributed to her.

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 the potential 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