DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: October 25, 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 Christy Sanborg, M.D.

I am writing to request a waiver for Christy Sanborg, M.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. Sanborg 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. Sanborg 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 herself, 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. Sanborg 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. Sanborg has advised the Food and Drug Administration that ———— has a financial interest that could potentially be affected by her participation in the matter at issue. **Dr. Sanborg's ——— serves as a consultant to ——— on diabetes related devices. ———— receives minimal compensation from this firm. ————————, a competing product to Celebrex, is———————— by ————————.**

As a voting consultant advising the Arthritis Drugs Advisory Committee, Dr. Sanborg potentially could become involved in matters that could affect her financial interest. Under 18 U.S.C. §208(a), 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. Sanborg 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. Sanborg, which would permit her to participate in the matter previously described.

First, Dr. Sandborg's ——— interest is not so substantial. ——— receives minimal compensation from ———.

Second, Dr. Sandborg's ——— interest in ——— is unrelated to the product coming before the committee, or the competing products.

Third, the uniqueness of Dr. Sanborg's qualification justifies granting this waiver. Dr. Sandborg has been in the field of pediatric rheumatology for over 35 years. She has published extensively in peer-reviewed journals, chapters in major rheumatology texts. She has been the invited presenter for major academic meetings, and has significant clinical trial experience. As the application from Pfizer is proposed for the pediatric population, Dr. Sandborg's insight on the treatment of patients with JRA, as well as the feasibility of conducting trials in this patient population would make a valuable contribution to the discussion of the committee which would be extremely helpful to the Division. She is well-positioned on state of the art clinical and health care delivery. We feel that she is critical to the success of the meeting and would contribute significantly in this environment, as well as help meet the obligation of the FDA's advisory panels in providing analytical and clinical expertise required to advise the agency in an objective, sound manner. Her opinion and expertise would be of significant contribution to the meeting in which the committee will deliberate the approval of a product intended to alleviate pain and other symptoms associated with juvenile rheumatoid arthritis in a pediatric population in which she is very familiar with.

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. Sanborg is Professor of Pediatrics at Stanford University School of Medicine where her research focuses on clinical studies and clinical trials in systemic onset juvenile arthritis

and pediatric Systemic Lupus Erythematosus (SLE). She is the Director of the Child Health Research Program at Lucile Salter Children's Hospital and Stanford School of Medicine, as well a the Director of the Division of Pediatric Rheumatology. She is an internationally recognized leader in pediatric rheumatology, advocacy, education and research. She has served on many national committees, including the American Board of Pediatrics Subboard of Rheumatology, the American College of Rheumatology Board of Directors and other committees, local and national Arthritis Foundation in many capacities, and several NIH Special Study Sections and invited workshops. She has been a member of the scientific advisory committees of several foundations, including the Lupus Foundation of America, the Arthritis Foundation Southern California Chapter, and the Lupus Clinical Trials Consortium. She is one of the founders and current Chair of the Childhood Arthritis and Rheumatology Research Alliance, a network of pediatric rheumatologists in the US and Canada dedicated to clinical and translational research in pediatric rheumatic diseases. I believe her 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 Christy Sanborg, M.D., a voting consultant, a waiver that will permit her 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 Christy Sanborg, M.D., outweighs the potential for a conflict of interest created by the financial interest attributable 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 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