DEPARTMENT OF HEALTH & HUMAN SERVICES

**MEMORANDUM**

Food and Drug Administration
Rockville MD 20857

**DATE:** February 8, 2006

**TO:** Jason D. Brodsky
Acting Associate Commissioner
Office of External Relations
Food and Drug Administration

**THROUGH:** Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

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

**SUBJECT:** Conflict of Interest Waiver for Peter Adamson, M.D.

I am writing to request a waiver for Peter Adamson, M.D. a consultant to the Center for Drug Evaluations 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. Adamson 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. Adamson 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 negotiating for, or as an arrangement concerning, prospective employment.

Dr. Adamson has been invited to participate in the Pediatric Subcommitte of the Oncologic Drugs Advisory Committee meeting to discuss clinical trials of daunomycin to be conducted under the Best Pharmaceuticals for Children Act. Cerubidine (daunorubicin, daunomycin) is sponsored by Bedford Laboratories, a division of Ben Venue Laboratories, Inc., a wholly owned subsidiary of Boehringer Ingelheim Corporation, the U.S. affiliate of Boehringer Ingelheim GmbH.

The function of the Oncologic Drugs 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 cancer, and to make appropriate recommendations to the Commissioner of Food and Drugs. Temporary subcommittees consisting of two or more committee members may be established as needed to address specific issues within their respective areas of expertise. Subcommittees make preliminary recommendations regarding specific issues for subsequent action by the full Committee.

**Dr. Adamson has advised the Food and Drug Administration that he and _____ have financial interests that could potentially be affected by his participation in the matter previously described. Dr. Adamson and _____ jointly own stock in _____ a competing to product to Cerubidine, is manufactured for _____ marketed by _____ a competing product to Cerubidine.**

**Dr. Adamson _____ has a managed retirement account that contains stock in _____ are competing products to Cerubidine.**

As a consultant advising the Pediatric Subcommittee of thee Oncologic Drugs Advisory Committee, Dr. Adamson potentially could become involved in matters that could

affect his and [redacted] 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. Adamson 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. Adamson that would permit him to participate in the matter previously described.

First, Dr. Adamson and [redacted] stock interests are not so substantial as to be deemed likely to affect his impartiality in this matter. The value of the stocks represents less than 5% of their total net worth.

Moreover, Dr. Adamson's expertise as Director of Experimental Therapeutics in Oncology, specializing in investigational new drugs to treat childhood cancer is essential to the subcommittee's discussions regarding clinical trials of daunomycin to be conducted under the Best Pharmaceuticals for Children Act.

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. Adamson'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. Peter Adamson is Chief of the Division of Clinical Pharmacology & Therapeutics at the Children's Hospital of Philadelphia. He is board certified in Pediatrics, Pediatrics Hematology/Oncology and Clinical Pharmacology. His special interest is in investigational new drugs for childhood cancer. He has received many awards and peer reviewed over 100 articles. He is a member of numerous Professional and Scientific societies and Academic committees, such as the American Society for Clinical Pharmacology and Therapeutics, American Society of

Clinical Oncology, Children's Hospital of Philadelphia Research Compliance Oversight Committee. I believe that Dr. Adamson's expertise in investigational new drugs to treat childhood cancer will contribute to the diversity of opinions and expertise represented on the committees and will provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant Peter Adamson, M.D., a waiver that will permit him to participate in all official matters concerning discussions of clinical trials of daunomycin to be conducted under the Best Pharmaceuticals for Children Act. Cerubidine (daunorubicin, daunomycin) is sponsored by Bedford Laboratories, a division of Ben Venue Laboratories, Inc., a wholly owned subsidiary of Boehringer Ingelheim Corporation, the U.S. affiliate of Boehringer Ingelheim GmbH. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Adamson outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: _____ 2/16/06

Jenny Slaughter
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 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.

_____ 2/27/06

Jason D. Brodsky
Acting Associate Commissioner
Office of External Relations
Food and Drug Administration

Date