DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: November 6, 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 overall benefit to risk considerations for the approved product, Ketek (telithromycin), new drug application (NDA) 21-144, manufactured by Sanofi-Aventis with the current indications of acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia. This issue is coming before a joint meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee and is considered a particular matter involving specific parties.

The committees' functions, as stated in their Charters, are as follows: The Anti-Infective 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 infectious diseases and disorders. The Drug Safety and Risk Management Advisory Committee is to advise the Commissioner of Food and Drugs on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The committees make their 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 is a consultant to ——— and ————————. According to Dr. Morris, these activities are unrelated to the matter coming before the committee or the competing products. Dr. Morris receives minimal compensation for his services. ——————— ——————— and ——————————— manufacture competing products to Ketek (telithromycin).**

Further, in December 2005 Dr. Morris consulted for ——————————— on a matter unrelated to Ketek and its competing products. He received a substantial fee for this work that has been completed.

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 such matters as you deem appropriate.

First, arguably Dr. Morris' past and current consulting activities do not constitute financial interests in the particular matter within the meaning of 18 U.S.C.§ 208(a), since he consults on matters unrelated to Ketek and its competing products. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Second, Dr. Morris' current interests in ——— and ——————————— are not so substantial as to preclude his participation in this matter. He receives minimal compensation for his current consulting activities.

Third, the uniqueness of Dr. Morris' qualification justifies granting this waiver. Dr. Morris is a highly regarded expert in the field of risk communication, especially as it relates to communicating risk of medications to patients. His expertise is valuable to the committee because the risks associated with the use of Ketek are complex and his views on appropriate ways to communicate these risks to patients will factor into the committees' risk-benefit profile of Ketek.

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, he 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 been 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 is on the editorial board of several pharmaceutical and marketing journals. Dr. Morris earned his doctoral degree in psychology from Tulane University. He was president of the Drug Information Association from 1994-1995 and 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 overall benefit to risk considerations for the approved product, Ketek (telithromycin), new drug application (NDA) 21-144, manufactured by Sanofi-Aventis with the current indications of acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia. 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/ 11/22/06

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/ 11/22/06

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

Date