



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

DATE: January 23, 2008

TO: Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

THROUGH: Vince Tolino   /S    
Director, Ethics and Integrity Staff  
Office of Management Programs  
Office of Management

Michael F. Ortwerth, Ph.D.   /S    
Deputy Director, Advisory Committee Oversight and Management Staff  
Office of Policy, Planning, and Preparedness

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

SUBJECT: 712(c)(2)(B) Conflict of Interest Waiver for James C. Eisenach, M.D.

I am writing to request a waiver for James C. Eisenach, M.D., a temporary voting member of the Anesthetic and Life Support Drugs Advisory Committee, from the conflict of interest prohibitions of section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act. Waivers under section 712(c)(2)(B) may be granted by the appointing official where it is "necessary to afford the advisory committee essential expertise" and where the individual has made a disclosure to FDA of the financial interests at issue. We have determined that you are the appointing official for purposes of section 712(c)(2)(B). Therefore, you have the authority to grant Dr. James Eisenach a waiver under section 712(c)(2)(B).

Section 712(c)(2)(A) prohibits Federal executive branch employees, including special Government employees, from participating in any particular matter in which the employee or an immediate family member has a financial interest that could be affected by the advice given to the FDA with respect to the matter. Because Dr. Eisenach is a special Government employee, he is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him.

The function of the Anesthetic and Life Support 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 anesthesiology and surgery and make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. James Eisenach has been asked to participate on March 11, 2008, to discuss new drug application NDA 22-225, sugammadex sodium injection (Org25969), proposed trade name Bridion, sponsored by Organon USA, a subsidiary of Schering-Plough Corporation, proposed indication of routine reversal of shallow and profound neuromuscular blockade (NMB) induced by rocuronium or vecuronium and immediate reversal of NMB at 3 minutes after administration of rocuronium.

This matter is coming before a meeting of the Anesthetic and Life Support Drugs Advisory Committee. This issue is a particular matter involving specific parties.

Dr. Eisenach has advised the Food and Drug Administration (FDA) that he has a financial interest that could potentially be affected by his participation in the matter described above. Dr. Eisenach is a consultant to \_\_\_\_\_ on an unrelated issue. \_\_\_\_\_, a subsidiary of \_\_\_\_\_ is the sponsor of \_\_\_\_\_, the product \_\_\_\_\_ and \_\_\_\_\_, a competing product.

As a temporary member to the Anesthetic and Life Support Drugs Advisory Committee, Dr. Eisenach could become involved in matters that could affect his financial interest. Under section 712(c)(2)(A), he is prohibited from participating in such matters. However, as noted above, you have the authority under section 712(c)(2)(B) to grant a waiver permitting Dr. James Eisenach to participate in such matters if necessary to afford this committee essential expertise.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. James Eisenach that would allow him to participate fully in the matter described because his voting participation is necessary to afford the committee essential expertise.

James C. Eisenach, M.D., is Professor of Anesthesiology as well as Physiology and Pharmacology at Wake Forest University in North Carolina Baptist Medical Center, where he is also the Vice Chairman for Research in the Department of Anesthesiology and a member of the Graduate Faculty for the Molecular Medicine Program. At Wake Forest he is recognized as a savvy and skillful clinical anesthesiologist in the surgical, obstetrical and pain management arenas. He has served at the national level on multiple committees. Most relevant of which for this ALSDAC meeting are the Board of Directors for the Society for Obstetric Anesthesia and Perinatology, Scientific Advisory Board for the Association of University Anesthesiologists, and the American Society of Regional Anesthesia and Pain Medicine. In addition, Dr. Eisenach has served on the ALSDAC in the past and has been a consultant to the Gastrointestinal Drugs Advisory Committee. At NIH, he has served on the Advisory Panel for Funding Directions at the National Institute of General Medical Sciences (NIGMS) and on the Speaker and Advisory Panel for Funding in Biomarkers and Surrogate Outcomes.

Dr. Eisenach's current research interests are in the areas of obstetrical anesthesia with an emphasis on the management of labor pain and the impact of anesthesia on the fetus. This research has included evaluation of ST segment depression during cesarean section, and the assessment of pharmacokinetic and pharmacodynamic parameters of anesthetic drugs in animal models.

Fourteen anesthesiologists, with similar but not identical, expertise, were invited to participate. Five cannot attend due to schedule conflicts and one is recused. Of the eight planning to attend, Dr. Eisenach is the only one with Obstetric Anesthesia and Perinatology expertise. His presence on the ALSDAC when it meets to consider the safety and efficacy of Bridion will allow input from an individual who is uniquely qualified to raise and address concerns related to the pregnant patient, the fetus and the newborn especially those that require a substantial knowledge of pharmacodynamics, pharmacokinetics, and electrocardiographic activity in these special patient populations.

Moreover, 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 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.

Accordingly, I recommend that you grant James C. Eisenach, M.D., a waiver that would allow his voting participation in all official matters concerning new drug application NDA 22-225, sugammadex sodium injection (Org25969) proposed trade name Bridion, sponsored by Organon USA, a subsidiary of Schering-Plough Corporation, proposed indication of routine reversal of shallow and profound neuromuscular blockade (NMB) inducted by rocuronium or vecuronium and immediate reversal of NMB at 3 minutes after administration of rocuronium. I believe that such a waiver is appropriate because in this case, Dr. James Eisenach's voting participation is necessary to afford the committee essential expertise.

DECISION:

Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that voting participation is necessary to afford the committee/panel essential expertise.

Waiver granted based on my determination, made in accordance with section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, that nonvoting participation is necessary to afford the committee/panel essential expertise

Waiver denied.

RS  
Randall W. Lutter, Ph.D.  
Deputy Commissioner for Policy  
Food and Drug Administration

2/5/08  
Date