



DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration  
Rockville MD 20857

**DATE:** December 20, 2005

**TO:** Sheila Dearybury Walcoff, Esq.  
Associate Commissioner for 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 Nancy Sander

I am writing to request a waiver for Nancy Sander, a consultant to the Center for Drug Evaluation and Research, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official 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 Ms. Sander 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 Nancy Sander 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 as an arrangement concerning, prospective employment.

2006-4200 WL-03-SANDER-208

Nancy Sander has been asked to participate in all official matters concerning discussions of the continued need for the designation of over-the-counter (OTC) epinephrine-metered dose inhalers (MDIs) for the treatment of asthma as an essential use of ozone-depleting substances under 21 CFR 2.125. The committees' discussions will not focus on any particular product or sponsor and are a particular matter of general applicability. This matter is coming before the Nonprescription Drugs Advisory Committee and the Pulmonary Allergy Drugs Advisory Committee for consideration.

The function of the Nonprescription Drugs Advisory Committee is to review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee also serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof.

The function of the Pulmonary Allergy 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 pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs.

Nancy Sander has advised the Food and Drug Administration that she has financial interests that could potentially be affected by her participation in the matter described above. Ms. Sander owns stock in [REDACTED]. [REDACTED] is one of the products that could potentially be affected by the committees' discussions.

In addition, Ms. Sander is a member of [REDACTED] [REDACTED] Advisory Board on anaphylaxis. She has an upcoming meeting scheduled December 17, 2005 and anticipates receiving a nominal fee for her participation. [REDACTED] is a product that could be affected by the committees' discussions.

As a consultant participating in the joint meeting of Nonprescription Drugs Advisory Committee and Pulmonary-Allergy Drugs Advisory Committee, Ms. Sander potentially could become involved in matters that could affect her financial interests. Under 18 U.S.C. §208(a), she is prohibited from participating in such matters. However, as noted above, you have the authority under section 208(b)(3) to grant a waiver permitting Ms. Sander 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 Ms. Sander that would permit her to participate all official matters concerning the committees' discussions of the continued need for the designation of OTC epinephrine-metered dose inhalers for the treatment of asthma as an essential use of ozone-depleting substances under 21 CFR 2.125.

First and foremost, this waiver is justified, in part, because of the general nature of particular matters of general applicability. It is well recognized that particular matters of general applicability pose far less risk of a conflict of interest because they do not focus on any particular product or sponsor. Ms. Sander's participation in the discussions will not have a unique and distinct impact on any of her personal financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent.

Second, this waiver is justified because arguably, Ms. Sander's advisory board activities do not constitute a financial interest in the particular matter of general applicability within the meaning of 18 U.S.C. §208(a), since the board advises on issues unrelated to the

products that could be affected by the committees' deliberations. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

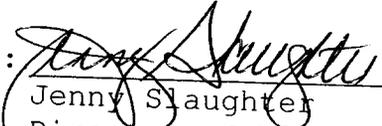
Third, Ms. Sander's financial interests are not so substantial as to preclude her participation in the committees' discussions. She receives modest compensation for these activities.

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 various advisory committee members and Ms. Sander's participation as a patient representative will contribute to the balance of views represented and the diversity of opinions and expertise. 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. Nancy Sander is President and Founder of Allergy & Asthma Network Mothers of Asthmatics (AANMA), a nationwide community-based nonprofit health organization dedicated to eliminating morbidity and mortality due to asthma and allergies through education, advocacy, community outreach, and research. Through caring for asthmatic daughter, Ms. Sander became an expert on the practical aspects of parenting a child with asthma and allergies. In 1985, Ms. Sander founded AANMA, a network to give other parents the coping strategies, medical information and the emotional support she found so useful in managing her daughter's condition. The AANMA provides patient education services including a quarterly magazine, newsletters, and seminars for medical professionals and families, publications and videos, and a toll-free hotline. Ms. Sander is often called upon to represent the patient's perspective at pharmaceutical or device manufacturer sponsored meetings. She has served in this capacity periodically over the last 20 years. Ms. Sander speaks at conferences, conventions, and family support group meetings across the county and also testifies at the national and state level on patient rights to safe, reliable medications and health care. She participates on numerous asthma-allergy related committees, boards and government panels.

She received a Lifetime Service Award from the Louisiana State Allergy Asthma & Immunology Society. Ms. Sander is the editor-in-chief of *Allergy & Asthma Today* magazine and *The MA Report*, AANMA's monthly newsletter. In addition, she has written numerous books and articles and has produced many children's books and videos. I believe that Ms. Sander's participation as a patient representative will provide insight on issues, problems, and/or questions pertinent to the viewpoint of patients and family members living with asthma.

Accordingly, I recommend that you grant Nancy Sander a waiver that will permit her to participate in all official matters concerning the committees' discussions of the continued need for the designation of over-the-counter epinephrine-metered dose inhalers for the treatment of asthma as an essential use of ozone-depleting substances under 21 CFR 2.125. I believe that such a waiver is appropriate because in this case, the need for the services of Nancy Sander outweighs the potential for a conflict of interest created by the financial interests attributable to her.

CONCURRENCE:

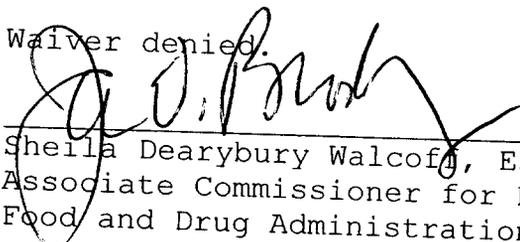
  
Jenny Slaughter  
Director, Ethics and  
Integrity Staff  
Office of Management Programs  
Office of Management

12/27/05  
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.

  
Sheila Dearybury Walcoff, Esq.  
Associate Commissioner for External Relations  
Food and Drug Administration

12/29/05  
Date