DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Rockville MD 20857

DATE: December 22, 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 David Schoenfeld, Ph.D.

I am writing to request a waiver for David Schoenfeld, Ph.D., a member of the Pulmonary Allergy Drugs 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. Schoenfeld 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. Schoenfeld 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

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negotiating for, or as an arrangement concerning, prospective employment.

Dr. Schoenfeld 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 (ODSs) 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 a joint meeting of 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 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 to make appropriate recommendations to the Commissioner of Food and Drugs.

Dr. Schoenfeld has advised the Food and Drug Administration that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. David Schoenfeld is [redacted] and [redacted] of [redacted], a Clinical Research

Organization (CRO). He is on the board of directors, but he has no day to day responsibilities in directing the company. He does work part-time on some of [redacted] contracts for an hourly fee.

[redacted] has agreement with [redacted] for a study of a product unrelated to products that could be affected by the committees' discussions. Dr. Schoenfeld has no role in this interest.

In addition, [redacted] has a contract with [redacted] for a study of a product unrelated to products that could be affected by the committees' discussions. Dr. Schoenfeld will receive modest compensation for performing the statistical analysis.

As a member of the Pulmonary Allergy Drugs Advisory Committee, Dr. Schoenfeld 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. Schoenfeld 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. Schoenfeld that would permit him to participate in the matters previously described.

First and foremost, this waiver is justified, in part, because of the general nature of particular matters of general applicability. Dr. Schoenfeld's participation in the committees' discussions of the continued need for the designation of OTC epinephrine-MDI's for the treatment of asthma as an essential use of ozone-depleting substances will not have a unique and distinct impact on any of his personal financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent. 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.

Second, this waiver is justified because arguably, Dr. Schonefeld's and [redacted] interests do not constitute financial interests in the particular matter of general applicability. Nevertheless, in the utmost of caution, I recommend that this waiver be granted.

Moreover, the amount of compensation that Dr. Schonenfeld receives for his consulting is not so substantial as to preclude his participation in the matter.

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. Schoenfeld's participation 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. Dr. Schoenfeld is Professor in the Department of Biostatistics, Harvard School of Medicine, Massachusetts General Hospital and Professor of Biostatistics in the Department of Medicine, HMS. Dr. Schoenfeld developed the first omnibus goodness of fit test for the proportional hazards regression model, a model that is used extensively in clinical trials which have survival or time to progression as an endpoint. He also developed widely used graphical techniques for this model. He authored a popular web site for sample size considerations for clinical trials. He directs the Clinical Coordinating Center for the ARDS Clinical Network, a national group doing clinical trials on Adult Respiratory Distress Syndrome. He collaborates with diverse groups at Massachusetts General Hospital, including the Clinical Research Center, many of the units in the Endocrine division, the Transplant Program, the Coordinating Center for the Cancer Genetics Network, and the Burn Unit. Dr. Schoenfeld's expertise is essential for an appropriate discussion of the public health benefit derived from the availability of over-the-counter epinephrine-metered dose inhalers for the treatment of asthma products in the OTC setting and the continued

need for the designation of these products as an essential use of ozone-depleting substances.

Accordingly, I recommend that you grant David Schoenfeld, Ph.D., a waiver that will permit him 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 Dr. Schoenfeld outweighs the potential for a conflict of interest created by the financial interests attributable to him.

CONCURRENCE: _____ 12/21/05

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.

_____ 12/29/05

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

Date