ULLMAN, SHAPIRO & ULLMAN, LLP

COUNSELORS AT LAW
299 BROADWAY, SUITE 1700
NEW YORK, NY 10007
TEL. (212) 571-0068
FAX. (212) 571-9424
www.usulaw.com
usu@usulaw.com

ROBERT ULLMAN
STEVEN SHAPIRO*
MARC S. ULLMAN

SETH A. FLAUM*○

TRADEMARK COUNSEL
DENNIS H. CAVANAUGH

BUSINESS & TECHNOLOGY COUNSEL
IRA R. HECHT*△†

OF COUNSEL
IRVING L. WIESEN

* ADMITTED IN NY & NJ
○ ADMITTED IN MD & DC
△ ADMITTED IN FL
† CPA

WASHINGTON AFFILIATE
JAMES M. JOHNSTONE
1776 K STREET, NW
WASHINGTON, DC 20006

WEDLAKE BELL
16 BEDFORD STREET
COVENT GARDEN
LONDON WC2E 9HF
ENGLAND

E.U. CORRESPONDENT
LAFILL VAN CROMBRUGGHE
& PARTNERS
VOSSENDREEF 6 BUS 1
B-1180 BRUSSELS,
BELGIUM

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VIA FACSIMILE (202) 225-4099 & FEDERAL EXPRESS

The Honorable Henry A. Waxman
2204 Rayburn House Office Building
Washington, D.C. 20515

Dear Rep. Waxman:

This morning I had occasion to attend your keynote presentation to the annual conference of the Food and Drug Law Institute. I found your comment on the need for honest, scientific based regulation particularly relevant and significant.

During your presentation, you stated that the Food and Drug Administration ("FDA") is in possession of evidence demonstrating that 100 deaths were "probably caused" by ephedra. This statement appears to conflict with the conclusions of the RAND Corporation's study of ephedra,[1] which reports that a comprehensive review of the public literature and all evidence in the possession of FDA revealed only two fatal "sentinel events" involving ephedra.[2]

In light of the important legal, regulatory and policy issues involving ephedra, I respectfully submit that it is extremely important for you to identify the additional 98 cases where ephedra "probably caused" fatal adverse events. Because FDA is presently in the process of promulgating regulations governing the sale of ephedra products, I urge you to release this information immediately. Such action will help ensure that the final regulations will be both honest and science based.

Respectfully yours,

ULLMAN, SHAPIRO & ULLMAN, LLP

Marc S. Ullman

[1] The Rand Report, entitled "Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects," was commissioned by the National Institute of Health to review evidence on the risks and benefits of ephedra and ephedrine. It was prepared for the U.S. Department of Health and Human Services and was released by FDA on February 28, 2003.

[2] Rand notes that the classification of a "sentinel event" does not imply a proven cause and effect relationship between the ephedra supplement and the adverse event, p. 89.