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\*NOT ADMITTED IN DC

January 26, 1999

**BY FACSIMILE/CONFIRMATION COPY BY HAND DELIVERY**

Nicholas P. Reuter  
 Associate Director for Domestic and International Drug Control  
 Office of Health Affairs (HFY-20)  
 Room 15-22  
 Food and Drug Administration  
 5600 Fishers Lane  
 Rockville, Maryland 20857

Re: International Drug Scheduling Recommendations, 64 Fed. Reg.  
 1629 (Jan. 11, 1999), Docket No. 98N-0148

Dear Mr. Reuter:

Hyman Phelps & McNamara, P.C. hereby requests a public meeting on the World Health Organization (WHO) recommendation to add ephedrine to Schedule IV under the 1971 Convention on Psychotropic Substances. See 64 Fed. Reg. 1629, 1629-30 (Jan. 11, 1999). We represent dietary supplement manufacturers and distributors that sell dietary supplements that contain extracts of the herb Ephedra. Ephedra extracts contain small amounts of naturally-occurring ephedrine and related alkaloids. The international scheduling of ephedrine may effectively decimate the market for dietary supplements that contain Ephedra extracts. Accordingly, dietary supplement manufacturers and distributors have a strong policy interest in participating in FDA's formulation of United States policy with respect to the WHO scheduling recommendation.

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**There is an urgent need for a public hearing on the WHO scheduling recommendation for the following reasons:**

- 1. International scheduling cannot be justified on the virtual absence of evidence of ephedrine abuse.**
- 2. The timing of WHO and FDA actions makes it virtually impossible for the public, affected industry, or the United States government to address the policy implications of international ephedrine scheduling in any meaningful way prior to consideration by the United Nations Committee on Narcotic Drugs in March 1999.**
- 3. The international scheduling of ephedrine would subvert United States legal processes, and would render moot important ongoing policy debates in this country.**
- 4. The international scheduling of ephedrine will severely damage the cooperation that industry normally has accorded to domestic and international scheduling efforts.**
- 5. The public needs to ascertain FDA's position on the international scheduling of ephedrine.**

**Please inform us as soon as possible on the date that FDA intends to hold the public meeting.**

Sincerely,



A. Wes Siegner, Jr.

AWS/EER/tcc