



NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

Better Health
Through Responsible
Self-Medication

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January 12, 1999

Mr. Nicholas P. Reuter
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; WHO Scheduling Recommendations for Ephedrine, Dihydroetorphine, Remifentanil, and Certain Isomers
-- Docket No. 98N-0148

Dear Mr. Reuter:

The Nonprescription Drug Manufacturers Association would like to take this opportunity to request a public meeting concerning issues raised in FDA's January 11 *Federal Register* notice related to the World Health Organization recommendation that ephedrine be scheduled under the UN Convention on Psychotropic Substances.

We believe such a meeting would be useful and is indicated for three main reasons:

First, we would like to better understand the basis of the WHO recommendation. We have concerns with the recommendation, including its blurring of the roles of the UN Convention on Psychotropic Substances versus the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

Second, since the criteria under the UN Convention and for the WHO recommendation call for an assessment of the actual abuse and/or evidence of the likelihood of abuse of an ingredient balanced against an ingredient's usefulness, we would like to present our understanding of the U.S. situation.

Finally, as the *Federal Register* notice discusses, there are already a number of controls on ephedrine in the U.S., and they must be examined to determine whether they enable the U.S. to fulfill its Psychotropic Convention obligations. NDMA has extensive knowledge of the U.S. Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion and Control Act of 1993, the Comprehensive Methamphetamine Control Act of 1996, and the regulations to implement these amendments to the U.S. controlled substance framework.

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We would welcome the opportunity to provide information on these or other areas to assist FDA and the U.S. Government in preparing a position on ephedrine as the March UN Commission on Narcotic Drugs meeting approaches.

Sincerely,



David C. Spangler
Vice President - International
& Assistant General Counsel

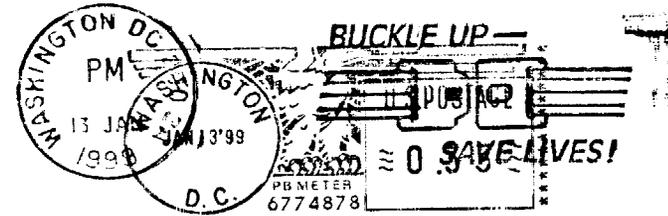
cc: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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