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A PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS

1722 EYE STREET, N.W.
WASHINGTON, D.C. 20006
TELEPHONE 202 736 8000
FACSIMILE 202 736 8711

FOUNDED 1866

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WRITER'S DIRECT NUMBER

March 5, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: WHO Scheduling Recommendations on Ephedrine (64 Fed. Reg. 1629, Jan. 11, 1999); Docket No. 98N-0148

Ladies/Gentlemen:

On behalf of the National Nutritional Foods Association (NNFA) of Newport Beach, California, the largest trade association of dietary supplement suppliers and retailers in the United States, we submit the following comments concerning the recommendation of the World Health Organization to impose international Schedule IV controlled substance requirements on ephedrine. Ephedrine is contained in many dietary supplement products sold in the U.S., having as its source the dietary ingredient ephedra.

NNFA strongly urges the U.S. Government to oppose the proposed scheduling of ephedrine at the upcoming meeting of the United Nations Convention on Narcotic Drugs in Vienna, to the extent it would impose restrictions on ephedrine-containing dietary supplements, for the following reasons.

1. There is no reliable scientific evidence that dietary supplements containing ephedrine have caused abuse or addiction at exising composition levels and recommended doses.

2. The FDA's Special Working Group on Food Products Containing Ephedrine found no definitive association between recommended dose levels of ephedra in dietary supplements and serious adverse effects.

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3. Several laws administered by the U.S. Drug Enforcement Administration (the Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion and Control Act of 1993, and the Comprehensive Methamphetamine Control Act of 1996) adequately address the potential for diversion of chemicals such as ephedrine for illicit manufacture of methamphetamine.

4. Commissioner of Food and Drugs Jane Henney recently indicated to a subcommittee of the U.S. Congress that the FDA is likely to regulate dietary supplements containing ephedrine separately from regulation of drugs containing ephedrine.

5. Dietary supplements are explicitly excluded from the provisions of the Food and Drug Modernization Act of 1997 relating to international regulatory harmonization. 21 U.S.C. § 383 (c)(5). Accordingly, any attempt to subject ephedrine-containing dietary supplements to international controlled substance scheduling requirements would contravene this statutory exemption.

Respectfully submitted,

NATIONAL NUTRITIONAL FOODS ASSOCIATION

Joe Bassett, President
Michael Q. Ford, Executive Director

SIDLEY & AUSTIN
General Counsel

By _____
Charles J. Raubicheck

cc: Nicholas P. Reuter
FDA Office of Health Affairs (HFY-20)

SIDLEY & AUSTIN
875 Third Avenue
New York, New York 10022

Phone (212) 906-2000
Fax (212) 906-2021

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