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Memorandum

VIA FAX

To: Nicholas P. Reuter
Office of Health Affairs
Food and Drug Administration

From: Robert E. Armstrong
Gronek & Armstrong

Date: March 1, 1999

Subject: Written Comments on World Health Organization
Recommendations on Ephedrine and Other Substances

Please add the attached written comments@ the record compiled on the recommendations by the World Health Organization (WHO) to impose International manufacturing and distributing restrictions under international treaties, on ephedrine and other drug substances. We ask that you consider these written comments together with our oral testimony given on February 19, 1999, in preparing the U.S. position on these proposals for the CND meeting in Vienna, Austria, on March 16 through 25, 1999.

Both Ruth Ann Box the General Counsel of AdvoCare and myself appreciate the opportunity to furnish our views on this matter of world wide importance.

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Re: WHO Scheduling Recommendations on Ephedrine
February 19, 1999****Written Comments of:
Robert E. Armstrong, Partner
Gronek & Armstrong**

The recommendations by the World Health Organization (WHO) to impose international manufacturing "and distributing restrictions, under international treaties, on ephedrine should include an exemption for dietary supplement products containing ephedrine alkaloids as a result of their ephedra content in order to ensure clarity and eliminate potential confusion regarding the inclusion of such products.

There currently exists much concern regarding the misuse and abuse of products containing ephedrine. As a result, many states have enacted or proposed laws, rules, and regulations that restrict access to such products. However, in the enactment or proposal of such laws, rules, and regulations, many states did not specifically distinguish between products containing chemical ephedrine and dietary supplement products containing ephedrine alkaloids from botanical sources. Although the majority of the states failing to provide such a distinction did not intend to include dietary supplement products within the scope of the enacted or proposed law, rule or regulation, much unnecessary confusion occurred as a result,

In all but one state, access to dietary supplements containing ephedrine alkaloids continues, albeit with some restrictions on labelling and content levels. States such as Arkansas, Florida, Illinois, Nevada, Ohio, Utah and Washington, as well as the City of Honolulu and Nassau County, New York have carved out specific requirements for these products so that the same are

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not systematically subject to **respective** restrictions regarding ephedrine products. In these states and municipalities, there **is** no confusion as to the regulation of **dietary** supplement products containing ephedrine alkaloids.

In addition, at least 2 states, Indiana and Texas, **have** proposed laws or rules which clearly **distinguish** between ephedrine-containing products and dietary supplement products containing ephedrine alkaloids from botanical sources.

In approximately 12 other states, **while** no specific exemptions for dietary supplement products exist in connection **with** respective laws restricting the sale of products containing ephedrine, "unofficial exemptions" for such products **exist** either because of **oral** representations or inaction by representatives of the enforcing **body**. In these states, much unnecessary **confusion existed, and continues to exist** with regard to dietary supplement products.

Nonetheless, it **is** clear that access to **such** products remains a priority; as demonstrated by some states' revision of their previously enacted ephedrine laws, rules, or regulations in order to incorporate a specific exemption for dietary supplement products containing ephedrine alkaloids for botanical sources, namely Ohio.

Thus, not only should the United States position on the WHO recommendation clearly advocate that it **not** apply to dietary supplement products containing botanical sources of ephedrine, alkaloids, but also that the recommendation clearly state the same in order to avoid misinterpretation. This position **is** not only consistent with the current **stance on such** products, but is essential to eliminate potential misinterpretation in the international arena and ensure continued access to botanical source **ephedra** dietary supplements.