

**ARTER & HADDEN<sub>LLP</sub>**

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January 25, 1999

**VIA FEDERAL EXPRESS**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; World Health Organization Scheduling recommendations for Ephedrine, Dihydroetorphine, Remifentanyl, and Certain Isomers; Docket No. 98N-0148

Dear Mr. Reuter:

This firm currently represents Metabolife International, Inc., a United States based corporation that manufactures and distributes dietary supplements. One of Metabolife's products, "Metabolife 356," is a dietary supplement which contains *ma huang*, an ephedrine alkaloid. Because of this product, Metabolife is extremely interested in the Food and Drug Administration's January 11, 1999 Federal Register notice concerning the World Health Organization's ("WHO") recommendation to schedule ephedrine under the United Nations Convention on Psychotropic Substances; thereby making products containing ephedrine available only by medical prescription. As a result, Metabolife requests a public meeting on the recommendations by the WHO to impose international manufacturing and distribution restrictions on ephedrine.

If the United Nations Commission on Narcotic Drugs adopts the WHO recommendation on ephedrine, the resulting restrictions would have a significant impact on the millions of people that currently rely on dietary supplements containing *mu huang* and would have a similar negative impact on companies, like Metabolife, that produce these products for the public. In light of these serious consequences, it is remarkable that the FDA Federal Register notice provides very little information and support for the position taken by WHO to schedule ephedrine. It is important that the United States position on this important issue be developed only after reviewing all information and considering all input from affected persons. Therefore, it is essential that FDA convene a public meeting to allow this information to be provided. Several key issues need further public discussion and documentation.

98N-0148

APES

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First, it is premature for the United States to support the scheduling of ephedrine when the national debate on the regulation of ephedrine-containing products is unresolved. FDA has currently proposed a rule concerning dietary supplements containing ephedrine. The proposed rule generated significant opposition from consumers of dietary supplement, scientists and industries that manufacture and distribute these supplements. In addition, the rule-making has attracted the interest of Congressional policy makers who have raised important issues regarding the appropriate regulation of ephedrine-containing products. With this debate in progress, it would be unwise and premature for the United States to support the proposed scheduling of ephedrine under the United Nations Convention on Psychotropic Substances.

Second, very little information has been made available concerning the deliberations of the 31<sup>st</sup> WHO Expert Committee on Drug Dependence which met in June, 1998. It is important for the United States to fully understand this committee's scope of review, the range of information evaluated by the committee, and the final basis for the committee's recommendations. To understand the weight the United States should give the WHO recommendations, stakeholders and other interested persons should be allowed to review and comment on the source, validity and accuracy of the information relied upon by the expert committee. As you know, a great deal of misinformation has been circulated concerning ephedrine. Many of the studies are inconclusive and some of the data compilations are based upon incorrect assumptions. The development of a United States policy on ephedrine-containing products should be based on studies and information that have been shown to be accurate, relevant and reliable.

Third, the FDA Federal Register notice contains excerpts from the WHO Expert Committee on Drug Dependence report which conclude that "combination products containing ephedrine in herbal preparations" have been abused in the United States. No information has been made available to support that conclusion. In fact, the dietary supplement industry has reviewed information available in the United States regarding potential abuse and had arrived at a very different conclusion. Because many of the suggested underlying reasons for strict regulation of ephedrine-containing products seem to be related to abuse (including the precursor arguments), it is essential that the information relied upon by the WHO expert committee be made public. Only after such information is made public and stakeholders have had the opportunity to debate its accuracy and reliability, should the United States engage in debating the issue of abuse at the upcoming United Nations Commission on Narcotic Drugs meeting in Vienna.

Metabolife appreciates the opportunity to comment on the need for a public meeting to assist in the development of the United States position on the WHO recommendations. The importance and impact of this position strongly support expanded public input. Metabolife urges the FDA to favorably respond to this request and schedule a public meeting to develop the information necessary to support an appropriate position for the United States at the upcoming

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meeting of the United Nations Commission on Narcotic Drugs. If you have any questions concerning this request, please contact me at your convenience.

Sincerely,

  
Allen P. Beinke

APB/lah

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Sincerely,

  
Allen P. Beinke

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