

January 24, 1999

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Nicholas P. Reuter
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane
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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 Dietary Supplement Safety and Science Coalition ("DSSSC" or "Coalition") would like to request a public meeting concerning the issues raised in the FDA's January 11, 1999, Federal Register notice related to the World Health Organization's ("WHO") recommendation to include ephedrine in Schedule IV under the UN Convention on Psychotropic Substances.

The DSSSC believes that a public meeting is not only warranted but necessary and will be helpful to the Secretary of HHS and the Secretary of State in formulating the United States position with regard to the international control of these substances for the following reasons:

First, the Federal Register notice at page 1630, states that "in the USA, combination products containing ephedrine in herbal preparations have been abused." This statement is not supported by valid evidence. Therefore, it is necessary to learn of, examine and evaluate exactly what evidence the WHO is using to support this statement and to present to the FDA evidence refuting this statement. This is particularly important in that we have recently learned that the FDA may have submitted documents to the WHO directed towards this statement which were not made public in the docket.

Second, it is essential that the United States delegation not only vote against the rule, but argue that the rule should not be voted on or at the very least contain an exemption for any combination products containing ephedrine. FDA currently has proposed a rule regarding

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dietary supplements containing ephedrine. Dietary Supplements Containing Ephedrine Alkaloids, 62 Fed. Reg. 30678 (1997) (to be codified at 21 C.F.R. pt. 111) (proposed June 4, 1997). That rule has been severely criticized by industry, individual consumers and scientists as well as the Small Business Administration. In addition, there have been questions about the rule raised by individual members of Congress and certain congressional committees including the House Committee on Science. To support the WHO's recommendation, which is more restrictive, would be inappropriate, set a dangerous precedent and may cause further inquiry by Congress.

Third, a meeting is necessary because of the lack of availability of any information regarding the deliberations of the expert committee who made this recommendation to the WHO and the lack of communication by the Agency regarding the substance and content of the expert committee meeting. In fact, in late June and early July of last year attempts were made by representatives of the Coalition to contact Dr. Michael Klein of the FDA, who attended this meeting as a technical advisor, in order to obtain further information as to the recommendation of the expert committee and the substantiation used by the committee to make such a recommendation. However, we were informed by Nick Reuter that Mr. Klein declined to comment on any of the proceedings, thus making it impossible for any of the affected parties to comment on the proceeding, understand the basis for the recommendation or to be able to meaningfully participate in a process that could have a substantial effect on industry. Moreover, despite an obligation to include such information in the docket so as to allow industry to file meaningful comments, the FDA has failed to include information they provided the WHO regarding this proposal.

Fourth, because the UN Convention requires an assessment of the actual abuse and or evidence of the likelihood of abuse of an ingredient, balanced against its usefulness, it is important that industry be able to provide to the Agency further information as to the many benefits that have been attributed to the ingestion of ephedrine containing dietary supplements.

Fifth, an open discussion between the industry members and the Agency to determine whether existing United States regulation of ephedrine is sufficient to meet its regulatory requirements under the Convention is necessary, particularly where at best questionable evidence exist indicating any abuse of ephedrine containing dietary supplements.

Finally, it is imperative that the FDA have an open dialogue with industry to discuss the exact definition and scope of the term "abuse" that is set forth in the docket. Last April, while the Coalition was preparing comments in response to the FDA's notice that the

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WHO expert committee would be discussing ephedrine, the FDA informed the Coalition that the WHO was not interested in any information regarding the use of ephedrine as a precursor chemical. However, the Coalition later learned that the expert committee in fact did consider this matter and that the DEA and the Texas Department of Health submitted comments regarding this very issue. If the DSSSC had been properly informed of these facts, the Coalition would have been afforded an opportunity to demonstrate to the expert committee that dietary supplements containing ephedrine alkaloids are not being used as precursors to methamphetamine production and in fact it is impossible to convert multi-ingredient supplements into methamphetamine using common street methods. The Coalition has been actively involved in working with various state governmental agencies in developing state precursor chemical regulations. In virtually every case dietary supplement products have been exempted because there is no evidence that they are, will, or can be used as precursor chemicals. The Coalition would like to share its expertise and experience so as to educate the Agency on this matter.

The Coalition looks forward to the opportunity of meeting with you and other representatives of the FDA and the State Department who will be attending the meeting in March in Geneva, Switzerland, so that the delegation will be thoroughly prepared to object to this proposal and ensure that the position presented comports with the standards, laws and current position of the United States. Please respond to this request by February 10, 1999, so that we may have adequate time to respond to the WHO recommendation.

Sincerely,

A handwritten signature in black ink, appearing to read "Garry T. Pay". The signature is stylized and cursive, with a large initial "G" and "P".

Garry T. Pay
Executive Director
Dietary Supplement Safety and Science Coalition

cc: Dockets Management Branch (HFA-305)
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GTP:mfk