



HURLEY CONSULTING ASSOCIATES LTD.

08 May 2002

Dockets Management Branch (HFA-09305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

**RE: Docket No. 02N-0101**

Dear Sir/Madam:

Reference is made to the above Federal Register Notice dated 9 April 2002 entitled: International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Amfepramone (diethylpropion); Amineptine; Buprenorphine; Delta-9-tetrahydrocannabinol (dronabinol); Tramadol.

On behalf of UNIMED Pharmaceuticals, Inc., Hurley Consulting Associates Ltd., the authorized representative for Marinol® (dronabinol) is providing comments related to dronabinol.

If you have any questions, please contact the undersigned at (973) 701-1596.

Sincerely,

*Susan M. Mondabaugh, Ph.D./miff*

Susan M. Mondabaugh, Ph.D.  
Vice President Regulatory Affairs

Enclosure

Copies to: Margaret E. Hurley, M.D., Hurley Consulting Associates Ltd.  
Jean-Louis Anspach, UNIMED Pharmaceuticals, Inc.

02N-0101

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**Docket No. 02N-0101**

**International Drug Scheduling; Convention  
On Psychotropic Substances;  
Single Convention on Narcotic Drugs;**

**Delta-9-tetrahydrocannabinol**

**(dronabinol)**

**Marinol®  
Capsules**

*08 May 2002*

**UNIMED Pharmaceuticals, Inc.  
A Solvay Pharmaceuticals, Inc. Company  
Four Parkway North, Suite 200  
Deerfield, IL 60015-2544**

Prepared by  
Hurley Consulting Associates Ltd.  
One Main Street  
Chatham, NJ 07928

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## LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

<u>Abbreviation</u>	<u>Definition</u>
AAPCC	American Association of Poison Control Centers
DAWN	Drug Abuse Warning Network

## **1.0 INTRODUCTION**

Dronabinol was approved in the US in 1985. Since market introduction, there has been no evidence of diversion of the product, and little potential for misuse or abuse.

The evaluation is based on the following information:

- Postmarketing surveillance;
- Literature;
- American Association of Poison Control Centers (AAPCC); and
- Drug Abuse Warning Network (DAWN) database.

## **2.0 LEGITIMATE USE OF THE SUBSTANCE**

### **2.1 Is the substance currently registered as a medical product?**

Yes, dronabinol is registered in the US and marketed as Marinol® capsules under NDA 18-651.

### **2.2 If the answer to 2.1 is no, is there other legitimate use of the substance?**

Not applicable.

### **2.3 If there is legitimate use of the substance, how is the substance supplied? (Imported/Manufactured in the country)**

Dronabinol is manufactured in the US.

## **3.0 ABUSE OF THE SUBSTANCE**

### **3.1 Is the substance abused or misused in your country?**

No, there is little evidence of abuse or misuse of dronabinol in the US.

### **3.2 If yes, any information on the extent of abuse?**

The abuse and misuse potential were obtained from the AAPCC for the time period of 1992 through 1994. During this time period, there were 6 cases of intentional exposure reported. In 1992, one case of abuse was reported. No intentional exposures were reported in 1993. In 1994, there were 5 cases of intentional exposure reported, 2 of which were abuse, and 3 suicide attempts.

A study conducted by Calhoun, Galloway, and Smith (1998) represents a comprehensive review of the data available in the literature, popular press, Internet web sites, databases, and from surveys. The authors concluded that there is little abuse potential for dronabinol.

Moreover, a search of the company safety database does not demonstrate any signals of abuse.

**3.3 Any information on the extent of public health or social problems associated with the abuse of the substance (statistics on cases of overdose deaths, dependence, etc.)?**

The available data indicate that dronabinol is not abused or misused in the US. A search of the DAWN database demonstrated that from 1988 to 1994, there were no mentions of dronabinol to emergency department facilities participating in the DAWN survey (Calhoun, Galloway, and Smith; 1998).

In contrast, the abuse and misuse of marijuana or cannabis is well-documented. Despite the widespread use of cannabis, in a study conducted by von Sydow et al (2001) in adolescents and young adults, the probability of developing abuse or dependence is 8%.

**4.0 ILLICIT ACTIVITIES INVOLVING THE SUBSTANCE**

**4.1 Any information on the nature and extent of illicit activities involving the substance (clandestine manufacture, smuggling, diversion, seizure, etc.)?**

There is no street market for dronabinol according to the study conducted by Calhoun, Galloway, and Smith (1998), and no evidence of clandestine manufacture, smuggling, diversion or seizure of dronabinol.

### References

Calhoun, Sarah R., Galloway, Gantt P., and Smith, David E. Abuse Potential of Dronabinol (Marinol®). *J Psych Drugs* 30:187-196;1998.

von Sydow, Kirsten, Leib, Roselind, Pfister, Hildegard, et al. *Drug and Alcohol Abuse* 64:347-361;2001.

HURLEY CONSULTING ASSOC  
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FOOD AND DRUG ADMINISTRATION  
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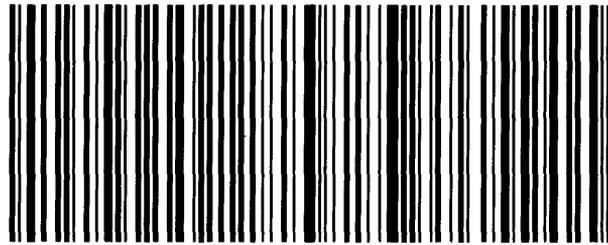
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