MARINOL® (dronabinol) Capsules CIII       Rescheduling Fact Sheet

All drugs regulated under the Controlled Substances Act (CSA) are placed into one of five schedules. Schedule I is reserved for the drugs with the greatest potential for abuse and that have no recognized medical use, while Schedule V is for drugs with the least potential for abuse. A drug receives a specific placement after being reviewed for the substance’s accepted medical use and potential for abuse or addiction\(^1\).

In 1999, the U.S. Drug Enforcement Administration (DEA), based in part from a concurring recommendation from the U.S. Department of Health and Human Services, reclassified MARINOL® (dronabinol) Capsules from a Schedule II controlled substance to Schedule III. This action was taken after thorough review of the abuse potential of MARINOL®, which found that the drug has lower abuse and addiction potential than drugs or substances in Schedules I and II\(^2\). The DEA also found little evidence of actual MARINOL® abuse, despite an increased number of prescriptions issued\(^3\).

**Schedule III Benefits\(^2\):**
As a Schedule III drug, MARINOL® is more accessible to patients, and simpler for physicians to prescribe and pharmacists to dispense:

- Physicians can phone in prescriptions to pharmacies.
- Patients are allowed five prescription refills over a period of six months.
- Pharmacists can simplify record keeping.

**State Regulations\(^2\):**
*For physicians to prescribe MARINOL® as a Schedule III product, each state also must approve the rescheduling. Following is a list of states that have approved MARINOL® as a Schedule III product:*


*As of September 2003, Oklahoma is the only state that has not yet adopted the federal rescheduling decision.*

\(^1\) *Controlled Substances Act, 2 U.S.C Section 801 (a), 811, 812.*

\(^2\) *“Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [D-9-(trans) - Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III” 64 Fed Reg 35928 - 35930 (July 2, 1999).*

\(^3\) 63 Fed Reg 59751 (Nov 5 1998)