21 CFR Part 1308
Schedule of Controlled Substances
Rescheduling of Synthetic Dihydrocodeine and
Soft Gelatin Capsules From Schedule I to Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule revising Schedule II to Schedule I.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is finalizing a rule to reschedule dihydrocodeine and 1,3-dihydroxy-6,7-dimethoxy-1,2,3,4-tetrahydroisoquinoline (Soft Gelatin Capsules) from Schedule I to Schedule II of the Controlled Substances Act (CSA). The Administrator, based upon the findings contained in section 131 of the CSA, determined that there is no unreasonable risk of dependency associated with the abuse of dihydrocodeine or 1,3-dihydroxy-6,7-dimethoxy-1,2,3,4-tetrahydroisoquinoline. The Administrator, therefore, is finalizing this rule which will provide for the registration of manufacturers, distributors, importers, and persons who dispense these substances.

This final rule will implement section 131 of the CSA and will be effective immediately upon publication in the Federal Register.

The final rule is based on the following four findings:

(A) The substances listed in this rule, dihydrocodeine and 1,3-dihydroxy-6,7-dimethoxy-1,2,3,4-tetrahydroisoquinoline, have a currently accepted medical use in treatment in the United States, are not included in the schedules of controlled substances set forth in section 305 of the CSA, and are not subject to any dispensing requirements under section 302 of the CSA.

(B) The substances listed in this rule, dihydrocodeine and 1,3-dihydroxy-6,7-dimethoxy-1,2,3,4-tetrahydroisoquinoline, have a currently accepted medical use in treatment in the United States, are not included in the schedules of controlled substances set forth in section 305 of the CSA, and are not subject to any dispensing requirements under section 302 of the CSA.

(C) The substances listed in this rule, dihydrocodeine and 1,3-dihydroxy-6,7-dimethoxy-1,2,3,4-tetrahydroisoquinoline, have a currently accepted medical use in treatment in the United States, are not included in the schedules of controlled substances set forth in section 305 of the CSA, and are not subject to any dispensing requirements under section 302 of the CSA.

(D) The substances listed in this rule, dihydrocodeine and 1,3-dihydroxy-6,7-dimethoxy-1,2,3,4-tetrahydroisoquinoline, have a currently accepted medical use in treatment in the United States, are not included in the schedules of controlled substances set forth in section 305 of the CSA, and are not subject to any dispensing requirements under section 302 of the CSA.

The final rule will take effect immediately upon publication in the Federal Register.

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