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Contact: DEA Public Affairs
(202) 307-7977

DEA to Publish Final Rule Rescheduling Hydrocodone Combination Products

AUG 21 (WASHINGTON)–On Friday the U. S. Drug Enforcement Administration (DEA) will publish in the *Federal Register* the Final Rule moving hydrocodone combination products (HCPs) from Schedule III to the more-restrictive Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) and as supported by the DEA's own evaluation of relevant data. The *Federal Register* has made the Final Rule available for preview on its website today at http://go.usa.gov/mc8d.

This Final Rule imposes the regulatory controls and sanctions applicable to Schedule II substances on those who handle or propose to handle HCPs. It goes into effect in 45 days**.**

The Controlled Substances Act (CSA) places substances with accepted medical uses into one of four schedules, with the substances with the highest potential for harm and abuse being placed in Schedule II, and substances with progressively less potential for harm and abuse being placed in Schedules III through V. (Schedule I is reserved for those controlled substances with no currently accepted medical use and lack of accepted safety for use.) HCPs are drugs that contain both hydrocodone, which by itself is a Schedule II drug, and specified amounts of other substances, such as acetaminophen or aspirin.

"Almost seven million Americans abuse controlled-substance prescription medications, including opioid painkillers, resulting in more deaths from prescription drug overdoses than auto accidents," said DEA Administrator Michele Leonhart, "Today's action recognizes that these products are some of the most addictive and potentially dangerous prescription medications available."

When Congress passed the CSA in 1970, it placed HCPs in Schedule III even though it had placed hydrocodone itself in Schedule II. The current analysis of HCPs by HHS and the DEA shows they have a high potential for abuse, and abuse may lead to severe psychological or physical dependence. Adding nonnarcotic substances like acetaminophen to hydrocodone does not diminish its abuse potential. The many findings by the DEA and HHS and the data that support these findings are presented in detail in the Final Rule on the website. Data and surveys from multiple federal and non-federal agencies show the extent of abuse of HCPs. For example, Monitoring the Future surveys of 8th, 10th, and 12th graders from 2002 to 2011 found that twice as many high school seniors used Vicodin®, an HCP, nonmedically as used OxyContin®, a Schedule II substance, which is more tightly controlled.

In general, substances placed under the control of the CSA since it was passed by Congress in 1970 are scheduled or rescheduled by the DEA, as required by the CSA and its implementing regulations, found in Title 21 of the Code of Federal Regulations. Scheduling or rescheduling of a substance can be initiated by the DEA, by the HHS Assistant Secretary of Health, or on the petition of any interested party. (Detailed information on the scheduling and rescheduling process can be found beginning on page 8 of *Drugs of Abuse* on the DEA's website at http://www.justice.gov/dea/pr/multimedia-library/publications/drug_of_abuse.pdf.)

The rescheduling of HCPs was initiated by a petition from a physician in 1999. The DEA submitted a request to HHS for a scientific and medical evaluation of HCPs and a scheduling recommendation. In 2013, the U. S. Food and Drug Administration held a public Advisory Committee meeting on the matter, and the committee voted to recommend rescheduling HCPs from Schedule III to Schedule II by a vote of 19 to 10. Consistent with the outcome of that vote, in December of 2013 HHS sent such a recommendation to the DEA. Two months later, on February 27, the DEA informed Americans of its intent to move HCPs from Schedule III to Schedule II by publishing a Notice of Proposed Rulemaking in the *Federal Register*, outlining its rationale and the proposed changes in detail and soliciting public comments on the proposal, of which almost 600 were received. A small majority of the commenters supported the proposed change.