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DEA Announces Actions Related to Marijuana and Industrial Hemp

AUG 11 (WASHINGTON) - The Drug Enforcement Administration (DEA) announced several marijuana- related actions, including actions regarding scientific research and scheduling of marijuana, as well as principles on the cultivation of industrial hemp under the Agricultural Act of 2014.

DEA Publishes Responses to Two Pending Petitions to Reschedule Marijuana

DEA has denied two petitions to reschedule marijuana under the Controlled Substances Act (CSA). In response to the petitions, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (HHS), which was conducted by the U.S. Food and Drug Administration (FDA) in consultation with the National Institute on Drug Abuse (NIDA). Based on the legal standards in the CSA, marijuana remains a schedule I controlled substance because it does not meet the criteria for currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

In his <u>letter</u> to the petitioners, DEA Acting Administrator Chuck Rosenberg offered a detailed response outlining the factual and legal basis for the denial of the petitions.

The full responses to the petitions can be found in the Federal Register. Response 1 AND Response 2

The DEA and the FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug (IND) applications are the most appropriate way to conduct research on the medicinal uses of marijuana. Furthermore, DEA and FDA believe that the drug approval process is the most appropriate way to assess whether a product derived from marijuana or its constituents is safe and effective and has an accepted medical use. This pathway allows the FDA the important ability to determine whether a product meets the FDA criteria for safety and effectiveness for approval.

Increasing the Number of Authorized Marijuana Manufacturers Supplying Researchers

DEA announced a policy change designed to foster research by expanding the number of DEA-registered marijuana manufacturers. This change should provide researchers with a more varied and robust supply of marijuana. At present, there is only one entity authorized to produce marijuana to supply researchers in the United States: the University of Mississippi, operating under a contract with NIDA. Consistent with the CSA and U.S. treaty obligations, DEA's new policy will allow additional entities to apply to become registered with DEA so that they may grow and distribute marijuana for FDA-authorized research purposes.

This change illustrates DEA's commitment to working together with the FDA and NIDA to facilitate research concerning marijuana and its components. DEA currently has 350 individuals registered to conduct research on marijuana and its components. Notably, DEA has approved every application for registration submitted by researchers seeking to use NIDA-supplied marijuana to conduct research that HHS determined to be scientifically meritorious.

Statement of Principles Concerning Industrial Hemp and the Agricultural Act of 2014

The U.S. Department of Agriculture (USDA), in consultation with DEA and the FDA, also released a statement of principles concerning provisions of the Agricultural Act of 2014 relating to the cultivation of industrial hemp. Industrial hemp is a low-concentration THC variety of the cannabis plant intended to be used for industrial purposes (e.g., fiber and seed). This <u>statement of principles</u> is intended to inform the public, including institutions of higher education and State departments of agriculture, how Federal law applies to activities associated with industrial hemp that is grown and cultivated in accordance with Section 7606 of the Agricultural Act of 2014.

This statement of principles outlines the legalized growing and cultivating of industrial hemp for research purposes under certain conditions, such as in states where growth and cultivation are legal under state law. The 2014 Act did not remove industrial hemp from the list of controlled substances and, with certain limited exceptions, the requirements of the Federal Food, Drug, and Cosmetic Act and the CSA continue to apply to industrial hemp-related activities. The statement of principles addresses questions including the extent to which private parties may grow industrial hemp as part of an agricultural pilot program, the circumstances under which the sale of hemp products is permitted, and other related topics.