DOJ—DEA Proposed Rule Stage

(GBL), the precursor to gammahydroxybutyric acid (GHB), as a List I chemical. Reflecting this change in stature, the Drug Enforcement Administration (DEA) is amending its regulation to reflect the status of GBL as a List I chemical subject to the requirements of the CSA and its regulations. Establishments of a threshold for GBL will be the subject of a separate rulemaking. Therefore, unless and until a threshold is established, any distribution of GBL is a regulated transaction as described by 21 CFR 1300.02(b)(28). All handlers of GBL must comply with the CSA regulatory requirements pertaining to List I chemicals as described in the body of this document.

Timetable:

Placement of Gamma-Butyrolactone in List I of the Controlled Substance Act (21 U.S.C. 802)

Final Rule 04/24/00 (65 FR 21645)

Threshold for Gamma-Butyrolactone
NPRM 10/00/01
NPRM Comment Period End 12/00/01

Regulatory Flexibility Analysis

Required: No

Small Entities Affected: No Government Levels Affected: None

Additional Information: DEA-199, DEA-

Agency Contact: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Washington, DC 20537

Phone: 202 307-7183 **RIN:** 1117–AA52

1677. INDUSTRIAL USE OF PRODUCTS AND MATERIALS DERIVED FROM CANNABIS PLANTS

Priority: Substantive, Nonsignificant **Legal Authority:** 21 USC 802; 21 USC 811; 21 USC 812; 21 USC 871(b)

CFR Citation: 21 CFR 1308 Legal Deadline: None

Abstract: DEA is planning to publish three rules simultaneously in the Federal Register regarding the status of products manufactured from the cannabis plant. It is anticipated that the three rules will be as follows.

The first rule will be an interpretive rule, which will provide DEA's interpretation of existing law with respect to the listing of tetrahydrocannabinols (THC) in Schedule I of the Controlled Substances Act (CSA) and DEA regulations. (Please see "Additional Information" for further details.)

The second rule will be a proposed rule, which will propose to revise the wording of the DEA regulations to more clearly reflect DEA's interpretation of the law as set forth in the interpretive rule. The proposed rule would make clear that the listing of THC in Schedule I includes both natural and synthetic THC and that any substance containing any amount of THC is a Schedule I controlled substance—even if such substance is made from "hemp."

The third rule will be an interim rule, which will exempt from application of the CSA and DEA regulations certain industrial "hemp" products. DEA would be issuing this rule to allow the continuation of what have historically been considered legitimate industrial uses of "hemp." Under this rule, industrial "hemp" products such as paper, rope, and clothing may continue to be marketed in the United States without being subject to the CSA. At the same time, in order to protect the public health and safety, the interim rule will not allow "hemp" products that result in THC entering the human body. In this manner, it will remain clear that the only lawful way THC may enter the human body is when a person is using a federally approved drug or when the person is the subject of federally approved research.

Timetable:

Clarification of Listing of Tetrahydrocannabinols NPRM 10/00/01

Exemption from Control of Certain Industrial Products and Material Derived From the Cannabis Plant Interim Final Rule 10/00/01

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Additional Information: While agencies are not required to include information regarding interpretive rules in the Unified Agenda, DEA is providing a description of this interpretive rule for informational purposes. The interpretive rule will provide DEA's interpretation of existing law with respect to the listing of tetrahydrocannabinols (THC) in

Schedule I of the Controlled Substances Act (CSA) and DEA regulations. The rule will further provide DEA's interpretation of the current legal status of products containing THC. In recent months, DEA has received numerous inquiries from members of the public about the legal status of products made from "hemp" (portions of the cannabis plant excluded from the CSA definition of marijuana). As stated in this rule, DEA interprets the CSA such that any substance containing any amount of THC is a Schedule I containing any amount of THC is a Schedule I controlled substance—even if such substance is made from "hemp."

Agency Contact: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Washington, DC 20537

Phone: 202 307-7183 **RIN:** 1117–AA55

1678. EXEMPTION FROM IMPORT/EXPORT REQUIREMENTS FOR PERSONAL MEDICAL USE

Priority: Substantive, Nonsignificant **Legal Authority:** 21 USC 821; 21 USC 822; 21 USC 823; 21 USC 824; 21 USC 871(b); 21 USC 875; 21 USC 877; 21 USC 956

CFR Citation: 21 CFR 1301 Legal Deadline: None

Abstract: DEA is proposing to amend its regulations to restrict to 50 dosage units the total quantity of Schedule II, III, IV, and V controlled substances that may be imported for personal medical use by United States (U.S.) residents entering the U.S. A dosage unit is considered by DEA to be the basic unit used to quantify the amount to be taken in normal usage. The proposed 50 dosage unit limit would not apply to a U.S. resident who has a valid U.S. practitioner's prescription. This proposed rulemaking implements and extends the provisions of the Controlled Substances Trafficking Prohibition Act of 1998.

Timetable:

Action	Date	FR Cite
NPRM	10/00/01	
NPRM Comment	12/00/01	
Period End		

Regulatory Flexibility Analysis Required: No