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NOTICE OF FEDERAL SCHEDULING ACTION

Chapter 329-11(d) of the Hawaii Revised Statutes ("HRS") states that if a substance is added, deleted or rescheduled under federal law and notice of the designation is given to the Department of Public Safety, then the Department of Public Safety shall recommend to the legislature that a corresponding change in Hawaii law be made. The Department of Public Safety shall similarly designate the substance as added, deleted, or rescheduled under this chapter, after the expiration of thirty days from publication in the Federal Register of a final order, and this change shall have the effect of law. If a substance is added, deleted, or rescheduled under this subsection, the control shall be temporary and, if the next regular session of the state legislature has not made the corresponding changes in this chapter, the temporary designation of the added, deleted, or rescheduled substance shall be nullified.

On August 28, 2020, the Department of Public Safety was given notice via publication in the Federal Register of an interim final order[1] that the following substance was deleted from Schedule V by the United States Drug Enforcement Administration ("DEA"):

Drug products in finished dosage formulations that have been approved by FDA and that contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols

This federal scheduling action removes the regulatory controls and the administrative, civil, and criminal sanctions applicable to schedule V controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle the drug products listed in this notice. The DEA placed an effective date of August 21, 2020 on this scheduling action[i].

[1] The final order was published in volume 85, number 163 of the Federal Register on August 21, 2020.

In accordance with chapter 329-11(d) of the HRS, the Department of Public Safety is temporarily deleting the aforementioned drug product listed in this notice from Schedule V in chapter 329-22 (e) of the HRS. This temporary deletion removes the regulatory controls and the administrative, civil, and criminal sanctions applicable to schedule V controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle the aforementioned drug products listed in this notice in the State of Hawaii.

Consequently, chapter 329-22 of the HRS is temporarily amended by deleting subsection (e) to read as follows:

~~(e) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the United States Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 per cent (w/w) residual tetrahydrocannabinol~~

For clarity purposes, this notice specifically applies to the FDA approved prescription drug Epidiolex and any generic versions of that drug that are FDA approved and contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols only. This notice should not be construed to change the legal status of cannabis, marijuana, tetrahydrocannabinols, and other marijuana related constituents, except for the narrow application to the “Approved cannabidiol drugs” listed in this notice. Furthermore, unless further notice is given, the controls under federal and state law pertaining to prescription drugs continue to apply to Epidiolex and any generic versions of that drug that are FDA approved and contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

The changes in this notice shall take effect on October 15, 2020, as required under chapter 329-11(d) HRS.

[i] Normally, the DEA uses their internal federal rulemaking process to amend the controlled substances schedules in federal law. At the conclusion of the federal rulemaking process, the DEA issues a “final order” or a “final rule” and publishes that

final order or rule in the Federal Register. In this case, the Congress enacted a federal law known as the Agriculture Improvement Act of 2018. Among the contents of the new law was a statutory change that removed the "approved cannabidiol drugs" listed in this notice from the federal drug schedules. Consequently, because the changes in the new federal law supersede the DEA's normal rulemaking process, the DEA said in its interim final order that changes to the federal drugs schedules have already occurred. The only reason an "interim" versus "final" order was issued was because the DEA wanted to review public comments about other issues, not related to this scheduling action, that are also listed in its interim final order. As such, the requirement to make a temporary corresponding change to Hawaii law as required in section 329-11(d) is satisfied by the DEA's interim final order and prompts issuance of this notice.