DAVID Y. IGE
GOVERNOR

STATE OF HAWAII
DEPARTMENT OF PUBLIC SAFETY
Narcotics Enforcement Division
3375 Koapaka Street, Ste. D100
Honolulu, Hawaii 96819

NOLAN P. ESPINDA
DIRECTOR

CATHY Y. ROSS
DEPUTY DIRECTOR
ADMINISTRATION

Jodie F. Maesaka-Hirata
DEPUTY DIRECTOR
CORRECTIONS

Renee R. Sonobe Hong
DEPUTY DIRECTOR
LAW ENFORCEMENT

No. Posted at the Office of the Lieutenant Governor on October 10, 2018

October 1, 2018

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 September 28, 2018, The Department of Public Safety was given notice via publication in the Federal Register of a final order[1] that the following substances were placed into Schedule V by the United States Drug Enforcement Administration ("DEA"):

A drug product in finished dosage formulation that has been approved by the U.S. 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 percent (w/w) residual tetrahydrocannabinols

This federal scheduling action imposes 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

[1] The final order was published in volume 83, number 189 of the Federal Register on September 28, 2018.

propose to handle the drug products listed in this notice. The DEA placed an effective date of September 28, 2018 on this scheduling action.

In accordance with chapter 329-11(d) of the HRS, the Department of Public Safety is temporarily adding the aforementioned drug product listed in this notice into Schedule V in chapter 329-22 (e) of the HRS. This temporary addition imposes 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. Furthermore, any material, compound, mixture, or preparation other than the drug products referred to in this notice that falls within the federal Controlled Substances Act (CSA) definition of marijuana set forth in 21 U.S.C. 802(16) and/ or the definition of marijuana in chapter 329-1 of the HRS, including any non-FDA-approved CBD extract that falls within such definition, remains a schedule I controlled substance under the CSA and chapter 329, HRS. Thus, persons who handle such items remain subject to the regulatory controls, and administrative, civil, and criminal sanctions, applicable to schedule I controlled substances set forth in the CSA and DEA regulations, as well as the applicable statutes and rules of the State of Hawaii.

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

(e) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. 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 percent (w/w) residual tetrahydrocannabinols

For clarity purposes, this temporary scheduling action allows for the newly approved drug, Epidiolex (and any generic versions of the same formulation that might be approved by the FDA in the future), to be temporarily approved for public marketing in the State of Hawaii. Epidiolex is a widely anticipated drug used for the treatment of seizure disorders.

The changes in this notice shall take effect on October 29, 2018, as required under chapter 329-11(d) HRS.