SENATOR CORY BOOKER
SENATOR RON WYDEN
SENATOR CHUCK SCHUMER

CANNABIS ADMINISTRATION & OPPORTUNITY ACT

DISCUSSION DRAFT

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The War on Drugs has been a war on people—particularly people of color. The *Cannabis Administration and Opportunity Act* aims to end the decades of harm inflicted on communities of color by removing cannabis from the federal list of controlled substances and empowering states to implement their own cannabis laws.

Federal cannabis reforms are especially urgent as more and more states legalize the adult and medical use of cannabis. To date, the adult use of cannabis is legal in 18 states, the District of Columbia, the Commonwealth of the Northern Mariana Islands, and Guam; and the medical use of cannabis is legal in 37 states, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands, with nearly all Americans living in a state where some form of cannabis is legal. These changes represent a dynamic shift in public opinion and support across the political spectrum. Today, more than 90 percent of Americans believe cannabis should be legal either for adult or medical use. Despite legalization under state law and broad public support for cannabis legalization, cannabis remains illegal under federal law.

By ending the failed federal prohibition of cannabis, the *Cannabis Administration and Opportunity Act* will ensure that Americans – especially Black and Brown Americans – no longer have to fear arrest or be barred from public housing or federal financial aid for higher education for using cannabis in states where it's legal. State-compliant cannabis businesses will finally be treated like other businesses and allowed access to essential financial services, like bank accounts and loans. Medical research will no longer be stifled.

But this alone is not enough. The *Cannabis Administration and Opportunity Act* includes restorative measures to lift up people and communities who were unfairly targeted in the War on Drugs. The bill automatically expunges federal non-violent marijuana crimes and allows an individual currently serving time in federal prison for non-violent marijuana crimes to petition a court for resentencing. The legislation also creates an "Opportunity Trust Fund" funded by federal cannabis tax revenue to reinvest in the communities most impacted by the failed War on Drugs, as well as helping to level the playing field for entrepreneurs of color who continue to face barriers of access to the industry. Importantly, the legislation also ends discrimination in federal public benefits for medical marijuana patients and adult use consumers.

The legislation preserves the integrity of state cannabis laws and provides a path for responsible federal regulation of the cannabis industry. Like with federal regulations on alcohol,

states can determine their own cannabis laws, but federal prohibition will no longer be an obstacle. Regulatory responsibility will be moved from the U.S. Drug Enforcement Agency (DEA) to the Alcohol and Tobacco Tax and Trade Bureau (TTB), the Bureau of Alcohol Tobacco Firearms and Explosives (ATF), as well as the Food and Drug Administration (FDA) to protect public health. Additionally, revenue generated by federal taxes will support restorative justice and public health and safety research.

U.S. Senators Cory Booker, D-N.J., Ron Wyden, D-Ore., and Chuck Schumer, D-N.Y., (collectively referred to in this document as the "Sponsoring Offices") are committed to turning the page on this sad chapter in American history and undoing the devastating consequences of current discriminatory cannabis policies. As such, they are seeking feedback from the public as they finalize their proposal. The *Cannabis Administration and Opportunity Act* discussion draft is a detailed legislative proposal meant to spur a robust discussion among stakeholders in order to inform the Sponsoring Offices as they work to craft a final legislative proposal. The Sponsoring Offices request comments from stakeholders and members of the public, including social and criminal justice advocates, industry stakeholders, members of the public health and law enforcement communities, members of Congress, federal officials, state and local officials, and others for review and comment.

While the Sponsoring Offices will accept comments at any time, they encourage stakeholders to submit comments in writing by **September 1, 2021** in order to ensure time for offices to consider comments before introducing a final legislative draft. Comments may be submitted to **Cannabis_Reform@finance.senate.gov**.

Please note that while the Sponsoring Offices do not intend to publicly post all submissions, details from comment letters may become part of the public record through the course of the legislative process. If a comment involves sensitive information, stakeholders may contact the Sponsoring Offices directly to discuss the appropriate way to securely submit such information.

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DECRIMINALIZATION OF CANNABIS, RECOGNITION OF STATE LAW CONTROLLING CANNABIS.

Background

Under present law and regulations, cannabis (marihuana[1]) is classified as a Schedule I controlled substance for purposes of the Controlled Substances Act (CSA).[2] Despite legalization of adult use and medical cannabis in states throughout the United States, this federal classification subjects cannabis consumers and businesses to potential civil and criminal penalties, as well as the risk of asset forfeiture under federal law.[3] This classification also prohibits the import and export of cannabis and significantly limits the ability to conduct cannabis-related research. Hemp containing less than 0.3 percent delta-9 tetrahydrocannabinol (THC) by weight is not treated as cannabis under the CSA, and the possession, production, and distribution of hemp is generally permitted in compliance with federal and state law.[4] Separate from its status under the CSA, federal law under the Federal Food, Drug, and Cosmetic Act also prohibits marketing cannabis or hemp for a medical or health use without approval of a new drug application for the use and prohibits marketing food and dietary supplements that contain cannabis or hemp.[5]

It's clear from current law in other contexts that we have the capacity to safely and responsibly regulate cannabis sales, possession, and use in a way that balances individual liberty with public health and safety. Alcohol is generally legal to possess, produce, and distribute under federal law (subject to certain tax, regulatory, and public health requirements on commercial activity). However, federal law establishes state primacy regarding the sale of alcohol into a state. Despite its legal status federally, any state may prohibit or regulate the sale of alcohol within its borders, and federal law prohibits the sale of alcohol in violation of state law. [6] Individuals involved in interstate trafficking of contraband alcohol may be subject to criminal penalties.[7] Federal law also establishes a minimum drinking age of 21 years, to be enacted and enforced by the states.[8]

Tobacco products are also generally legal to possess, produce, and distribute under federal law (subject to certain tax, regulatory, and public health requirements on commercial activity).

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[1] The term “marihuana” is used in the Controlled Substances Act to refer to cannabis or marijuana.

[2] 21 USC 812(c), Schedule I (c)(10).

[3] See 21 USC 841 *et seq*.

[4] 21 USC 802(16)(B).

[5] 21 USC 321, 355; *See also* O’Conner, Sean M. and Lietzan, Erika, The Surprising Reach of FDA Regulation of Cannabis Even After Descheduling, 63 *Am. Univ. Law Rev.* 3 (2019).

[6] See Chapter 6 of Title 27, (The Wilson Original Packages Act), 27 USC 122 (The Webb-Kenyon Act), 27 USC 122a (The Victims of Trafficking and Violence Protection Act of 2000).

[7] 18 USC 1952.

[8] 23 USC 158.

Federal law prohibits the unlawful possession or distribution of tobacco products in any state or local jurisdiction which do not bear evidence that tobacco excise taxes have been paid in accordance with local law.[9] Any person who sells more than 10,000 cigarettes in a single transaction is required to record detailed information about the purchaser and report certain information to the ATF, and other state and federal agencies, enforceable by criminal penalties.[10] In addition, federal law prohibits the retail shipment of tobacco products unless applicable state and local tobacco taxes have been paid on such products.[11] Federal law establishes a minimum age for the purchase or possession of tobacco products at 21 years of age, to be enacted and enforced by the states in coordination with the Food and Drug Administration.[12] Federal law also establishes requirements on tobacco product manufacturers, including payment of user fees, establishment registration, premarket review, and postmarket surveillance.[13] Finally, federal law prohibits the remote sales of tobacco products unless the seller can ensure that the purchaser is 21 years of age or older, and prohibits vending-machine sales of cigarettes except in adult-only facilities.[14]

Proposal

Removal from Controlled Substances Act, Transfer of Federal Agency Function.

Sec. 101 of the Discussion Draft would remove cannabis (marihuana) from the Controlled Substances Act and direct the Attorney General to remove cannabis from the list of controlled substances in regulation within 60 days of enactment. A new definition of “cannabis” would be established within the Federal Food Drug and Cosmetic Act (FFDCA) under title 21 of the U.S. Code, which establishes requirements for food, dietary supplements, drugs (including biologics), devices, cosmetics, and other substances such as tobacco. This definition would retain the existing exception for hemp.

The provision would also transfer primary agency jurisdiction over cannabis from the DEA to the FDA within the Department of Health and Human Services, TTB within the Treasury Department, and ATF, within the Department of Justice, as appropriate. This transfer of jurisdiction would generally follow similar agency responsibilities established for alcohol and tobacco, and the provision directs the heads of such agencies to enter into a memorandum of understanding regarding these responsibilities.

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[9] See Chapter 114 of Title 18, (Contraband Cigarette Trafficking Act).

[10] *Id.*

[11] See Chapter 10A of Title 15, (The Jenkins Act, Preventing All Cigarette Trafficking Act).

[12] 21 USC 387f(d)(5), 42 USC 300X-26.

[13] 21 USC 387e, 387j, 387k, 387s.

[14] 21 USC 387f(d)(4), 21 CFR 1140.14(a), 1140.16(c).

The Sponsoring Offices request comments on the new definition of "cannabis," including comments on—

- The appropriate way to measure the potency of cannabis and cannabis products;
- The interaction between the definition of "cannabis" and the definition of "hemp;"
- The interaction between the definition of "cannabis," "cannabis product," and FFDCA drugs containing cannabis;
- The appropriate classification and regulation of synthetically-derived THC; and
- Conforming amendments and interactions relating to the descheduling of cannabis and establishing a new definition outside of the Controlled Substances Act.

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The Sponsoring Offices also request comments on agency responsibilities, including—

- The appropriate division of responsibilities between FDA, TTB, and ATF, including ways to increase coordination between agencies and ways to reduce duplication of administrative and compliance burdens;
- Appropriations requests for various agencies involved in cannabis administration in order to ensure that those agencies have the necessary tools and resources to effectively carry out new responsibilities; and
- Whether FDA regulation of cannabis products should be funded through a user fee program or other funding model.

Recognition of State Law Controlling Cannabis, Establishment of Public Safety and Enforcement.

Sec. 111 of the Discussion Draft would recognize state law as controlling the possession, production, or distribution of cannabis. Notwithstanding federal decriminalization, shipment of cannabis into a state in violation of state law is prohibited. In addition, the provision retains criminal penalties in the case of illegal cannabis diversion. Cannabis diversion is defined as (1) the unlawful possession, production, distribution, or purchase of 10 pounds or more of cannabis in violation of federal or state law, or (2) the unauthorized possession of 10 pounds or more of cannabis in any state or local jurisdiction for which tax has not been paid in accordance with local law. The provision clarifies that a state may not prohibit the interstate commerce of cannabis transported through its borders for lawful delivery into another state.

The Sponsoring Offices believe cannabis reform must protect the rights of states that choose to legalize cannabis, as well as those that choose not to. Strong anti-diversion rules are necessary to ensure cannabis produced and sold in legal states is not illegally trafficked into other states with the purpose of circumventing state-level laws relating to the sale, production, or taxation of cannabis. The Sponsoring Offices request comments on states' rights and anti-diversion provisions, including—

- The appropriate quantitative thresholds regarding contraband cannabis;
- The appropriate penalties for violations of anti-diversion provisions;
- Effective coordination between federal and state law enforcement and tax administrators relating to diverted cannabis;
- The interaction between state primacy regarding cannabis regulation, and the need for interstate consistency for product standards and regulation, including any responsibilities that should be reserved explicitly for states or the federal government; and
- Rules relating to interstate commerce involving cannabis, including state-level taxation and interactions with state-level distribution systems.

Establishing Minimum Age, Restriction on Retail Sale

Section 301 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by Sec. 502(b) of the Discussion Draft would establish 21 years of age as the minimum age required to purchase cannabis. A related provision would limit any retail sales transaction to no more than 10 ounces of cannabis or the equivalent amount of any cannabis derivative. This provision is intended to prevent illegal actors from purchasing large quantities of cannabis at retail in a cannabis-legal state and illegally trafficking that cannabis into other states with the purpose of circumventing state-level laws relating to the sale, production, or taxation of cannabis. Federal and state law enforcement has faced similar enforcement challenges related to the smuggling of contraband cigarettes purchased at retail.[15]

[15] See *Illicit Tobacco: Various Schemes are Used to Evade Taxes and Fees*, Government Accountability Office, March 2011 (https://www.gao.gov/assets/gao-11-313.pdf). See also *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences*, National Research Council and Institute of Medicine, 2015 (https://www.nap.edu/catalog/19016/understanding-the-us-illicit-tobacco-market-characteristics-policy-context-and).

In addition to the request for comment above relating to trafficking in contraband cannabis, the Sponsoring Offices request comment on the retail sale age and quantity restrictions, including—

- Whether additional programs or resources are needed to aid states in enforcing a minimum age requirement or quantitative retail limitations,
- The interaction between state minimum age laws and use of medication containing cannabis by minors,
- Guidance on existing best practices by cannabis-legal states regarding minimum age enforcement,
- The interaction between state minimum age laws and limitations regarding non face-to-face transactions (discussed further in Sec. 501 of the draft), and
- The appropriate quantitative thresholds regarding the limit on retail sales of cannabis.

RESEARCH, TRAINING AND PREVENTION.

Background

Under present law and regulations, cannabis (marihuana) is classified as a Schedule I controlled substance for purposes of the CSA.[16] Due to its status as a Schedule I controlled substance, research into potential medical uses and other benefits or harms of cannabis is strictly limited. Present law requires a researcher to undergo approval by the DEA and FDA and procure cannabis only from federally-approved production facilities in cooperation with the National Institute on Drug Abuse (NIDA).[17] Researchers have stated that the cannabis produced for research is not comparable to cannabis used in adult-use and medicinal markets nationwide, and that the DEA's past failures to expand federally-approved production of cannabis have further limited the productivity of their research.[18] As a result of these strict limitations on research into cannabis, possible health benefits or harms of its use may remain unknown. Researchers have been prevented from studying the impairing effects of THC in order to develop effective tests for driving under the influence of cannabis, the effects of cannabis use on fetal development and other crucial gaps in our national understanding of this widely-used substance.

[16] 21 USC 812(c), Schedule I (c)(10).

[17] 21 USC 1301.18.

[18] Britt Erickson, *Cannabis Research Stalled by Federal Inaction*, Chemical and Engineering News, Volume 98, Issue 25 pub. June 29, 2020 (https://cen.acs.org/biological-chemistry/natural-products/Cannabis-research-stalled-federal-inaction/98/i25).

Proposal

Sec. 201 of the Discussion Draft would direct the Comptroller General to conduct an evaluation of the societal impact of legalization by states with adult-use of cannabis. Under this provision, the Government Accountability Office (GAO) evaluation is required to include a number of (or any change to) societal metrics that may be impacted by legalization, including traffic-related deaths and injuries, hospitalizations and poison control center calls, violent crime rates, employment statistics, rates of cannabis use, and various other criteria. The Comptroller General has two years to complete the evaluation and submit a report to Congress.

Sec. 202 of the Discussion Draft would direct the Department of Health and Human Services (HHS), in consultation with the National Institutes of Health, to conduct or support research on the impacts of cannabis. The research may encompass a variety of topics, including the effects of cannabis on the human brain, the impact on various health conditions, and identification of potential medical benefits and uses of cannabis. The Secretary of HHS is required to consider different types of cannabis in this research, as well as submit an annual report to Congress regarding an overview of the research conducted or supported.

Sec. 203 of the Discussion Draft would direct the Department of Transportation and HHS to collect data on cannabis-impaired driving and continue research to enable the development of an impairment standard for driving under the influence of cannabis. The Secretary of HHS, acting through the Director of the Centers for Disease Control and Prevention, shall also study public health prevention strategies, develop public education materials, and award up to five grants to states to collect data, raise awareness, and enhance the use of state data linkage systems with respect to impaired driving.

The Sponsoring Offices believe that cannabis research should be robustly funded and encouraged and that such research will provide significant public health and safety benefits. The Sponsoring Offices request comment on research, training, and prevention, including—

- The annual and long-term funding needs for such efforts;
- Whether programs can be designed to steer research dollars to Historically Black Colleges and Universities and other institutions associated with historically disadvantaged communities; and
- Additional areas that may benefit from research, including agriculture, environmental protection, worker health and safety, and other areas.

RESTORATIVE JUSTICE AND OPPORTUNITY PROGRAMS

Background

Under current law, the Schedule I status of cannabis results in a plethora of collateral consequences for both individuals and businesses operating in the state-legal cannabis industry. All but three states allow at least some use of cannabis for medical reasons. In addition, 18 states and the District of Columbia have eliminated state prohibitions on the adult use of cannabis for those age 21 or older.[19] Due to resource limitations, a Department of Justice policy, and an appropriations rider, federal cannabis prosecutions have decreased significantly.[20] However, because individuals and organizations engaged in state-authorized cannabis-related activities are in violation of the CSA, they face legal consequences such as adverse immigration outcomes and ineligibility for federal public benefits, including loans, grants, and other benefits.[21] Moreover, individuals with federal cannabis convictions face even greater challenges—they may be serving long sentences[22] or struggling to maintain steady employment and housing because of their criminal records.[23] And due to racial biases in arrests and prosecutions, these individuals are disproportionately likely to be people of color.[24]

Descheduling cannabis is a critical step towards achieving justice for those targeted and hard hit by the War on Drugs. But that alone is not enough. Title III of the Discussion Draft goes further by seeking to redress past harm and create opportunity for the future. It requires expungement of federal non-violent cannabis convictions and resentencing and encourages states and localities to do the same. It explicitly bars adverse effects on immigration and discrimination in the provision of any "federal public benefit," as defined in 8 U.S.C. Section 1611(c). Title III also creates new grant programs to fund nonprofits that provide services to those adversely impacted by the War on Drugs, and aid state and local efforts to create equitable licensing programs and make loans to small businesses in the cannabis industry.

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[19] Joanna R. Lampe, *The MORE Act: House Plans Historic Vote on Federal Marijuana Legalization*, Congressional Research Service, LSB10556, Nov. 25, 2020 (https://www.crs.gov/Reports/LSB10556?source=search&guid=2e1b0525e2564af79635511725fd4346&index=2).

[20] Joanna R. Lampe, *State Marijuana "Legalization" and Federal Drug Law: A Brief Overview for Congress,* Congressional Research Service, LSB10482, May 29, 2020 (https://www.crs.gov/Reports/LSB10482?source=search&guid=a750def045f24f23975eb6006d977ece&index=1).

[21] Joanna R. Lampe, *The MORE Act.*

[22] Joanna R. Lampe, *State Marijuana "Legalization".*

[23] Terry-Ann Craigie, Ames Grawert & Cameron Kimble, *Conviction, Imprisonment, and Lost Earnings*, Brennan Center for Justice, Sept. 15, 2020 (https://www.brennancenter.org/our-work/research-reports/conviction-imprisonment-and-lost-earnings-how-involvement-criminal); Jaboa Lake*, Preventing and Removing Barriers to Housing Security for People with Criminal Convictions*, Center for American Progress, April 4, 2021 (https://www.americanprogress.org/issues/poverty/news/2021/04/14/498053/preventing-removing-barriers-housing-security-people-criminal-convictions/).

[24] *Race and the Drug War*, Drug Policy Alliance (https://drugpolicy.org/issues/race-and-drug-war).

Proposal

Opportunity Trust Fund Programs and Small Business Administration Programs

Sec. 301 of the Discussion Draft creates three grant programs aimed at creating opportunity for those harmed by the War on Drugs. The Community Reinvestment Grant Program will fund nonprofits that provide services to individuals adversely impacted by the War on Drugs, such as job training, reentry services, and legal aid, among other services. The program will be administered by a newly established Cannabis Justice Office within the Office of Justice Programs at the Department of Justice. Sec. 301 also creates two programs to be implemented by the Small Business Administration (SBA). The Cannabis Opportunity Program will provide funding to eligible states and localities to make loans to assist small businesses in the cannabis industry owned by socially and economically disadvantaged individuals. The Equitable Licensing Grant Program will provide funding to eligible states and localities to implement cannabis licensing programs that minimize barriers for individuals adversely affected by the War on Drugs. To be eligible for these SBA grants, states and localities must take steps to create an automatic process to expunge criminal records for cannabis offenses and violations for individuals under criminal supervision for cannabis offenses.

Sec. 302 of the Discussion Draft renames the existing Comprehensive Opioid Abuse Grant Program, instead calling it the Comprehensive Opioid, Stimulant, and Substance Abuse Program. It amends the relevant sections of the Omnibus Crime Control and Safe Streets Act to make grants available to states and localities to address substance abuse generally, rather than just opioid abuse.

Sec. 303 of the Discussion Draft amends relevant sections of the Small Business Act and Small Business Investment Act to explicitly make SBA programs and services available to cannabis-related legitimate businesses and service providers.

The Sponsoring Offices are aware of additional proposals in the U.S. House of Representatives to expand the Opportunity Trust Fund programs to include SBA technical assistance and loans to socially and economically disadvantaged business owners outside of the cannabis industry. The Sponsoring Offices request comment on similar and additional Opportunity Trust Fund programs, including—

- Expansions similar to those proposed in the House bill to include SBA technical assistance and loans to socially and economically disadvantaged business owners outside of the cannabis industry; and
- Grants to certain business owners to offset administrative and compliance costs associated with the provisions of this Act.

Demographic Data of Cannabis Business Owners and Employees

Sec. 304 of the Discussion Draft provides that the Bureau of Labor Statistics shall regularly compile and publicize data on the demographics (e.g., age, race, educational attainment) of business owners and employees in the cannabis industry. The Discussion Draft requires that identifying information shall be kept confidential.

Resentencing and Expungement

Under this section, within one year of enactment, each federal district shall expunge any arrests and convictions, as well as adjudications of juvenile delinquency, for a non-violent federal cannabis offense. Each individual is to be notified by the federal district of their expungement. After the date of enactment, any individual with a prior conviction or adjudication of juvenile delinquency for a non-violent federal cannabis offense, who is not under a criminal justice sentence, may file a motion for expungement. Courts shall also seal all records related to a conviction or adjudication of juvenile delinquency that has been expunged.

In addition, this section allows any individual who is under a criminal justice sentence for a non-violent federal cannabis offense to obtain a sentencing review hearing. After the sentencing hearing, courts shall expunge each arrest, conviction, or adjudication of juvenile delinquency for a non-violent federal cannabis offense, vacate the existing sentence or disposition of juvenile delinquency, and seal all records relating to a conviction or adjudication that has been expunged.

An individual who received an expungement under this section may treat the arrest, conviction, or adjudication as if it never occurred, and shall be immune from any civil or criminal penalties related to perjury, false swearing, false statements, failure to disclose such arrest, conviction, or adjudication. However, an individual who received an aggravating role adjustment pursuant to the United States Sentencing Guideline 3B1.1(a) in relation to a federal cannabis offense conviction shall not be eligible for expungement of that conviction.

Lastly, the Comptroller General of the United States shall conduct a demographic study of individuals convicted of a federal cannabis offense. The study shall include information about the age, race, ethnicity, sex, gender identity, and the type of community such users dwell in. Within two years after the enactment of this Act, the Comptroller General shall report to Congress the results of the study.

No Discrimination in Provision of Federal Public Benefits

This section would prohibit individuals from being denied any federal public benefit, as defined in 8 U.S.C. 1611(c), on the basis of use or possession of cannabis or on the basis of a conviction or adjudication of juvenile delinquency for a cannabis offense. Additionally, federal agencies are prohibited from using past or present cannabis use as a basis for denying or rescinding a security clearance.

No Adverse Effect for Purposes of Immigration Laws

This section would prohibit cannabis from being considered a controlled substance for purposes of immigration laws. Under this provision, a non-citizen cannot be denied any benefit or protection under the immigration laws based on events relating to cannabis.

Provisions of Medical Cannabis Recommendations by the Department of Veterans Affairs and Indian Health Service

Under current law, Veterans Affairs and Indian Health Service health care workers are prohibited from providing patients with recommendations regarding medical marijuana legal under state law.[25] This provision requires the appropriate federal agencies to authorize physicians and other health care workers employed by the VA and IHS to provide recommendations and opinions regarding the use of cannabis or drugs containing cannabis.

TAXATION OF CANNABIS AND ESTABLISHMENT OF TRUST FUND

Background

Background on Taxation

Under present law, alcohol and tobacco products are subject to federal excise taxes as well as state excise taxes.[26] While cannabis businesses are subject to federal income taxes (including the limitation on deductions and credits under IRC 280E) and certain state excise taxes, cannabis products are not subject to any federal excise tax.[27]

Federal alcohol and tobacco taxes apply differently depending on the type of product. Some products are taxed based on volume (i.e., pounds, gallons, or number of cigarettes), while other taxes are based on potency (i.e., alcohol by volume), and others are based on a percentage of price (for example, certain cigars are taxed at roughly 50 percent of their sales price). The table below outlines general tax rates for alcohol and tobacco.

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[25] Letter Regarding Medical Marijuana from Susan Karol, Chief Medical Officer, Indian Health Service, June 6, 2011 (https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/2011_Letters/DTLLdated06062011.pdf); VHA Directive 1315, "Access to VHA Clinical Programs for Veterans Participating in State-Approved Marijuana Programs," December 8, 2017 (https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=5711).

[26] Cigarettes are generally taxed at a rate equal to $1.01 per pack, with similar rates applying to other tobacco products. Beer is generally subject to a tax of $18 per barrel, wine is generally subject to a tax of $1.07 per gallon, and spirits are generally subject to a rate of $13.50 per proof gallon.

[27] IRC 280E generally disallows federal income tax deductions claimed in connection with any trade or business that consists of trafficking in Schedule I or II controlled substances. Once descheduled and removed from the CSA, the prohibitions under 280E will no longer apply to cannabis businesses.

General Federal Alcohol Tax Rates

Product	General tax rate
Beer (IRC 5051)	$18 per barrel[28]
Distilled Spirits (IRC 5001)	$13.50 per proof gallon[29]
Wine (IRC 5041)	
Still wines 16% ABV or less	$1.07 per gallon
Still wines 16% to 21%	$1.57 per gallon
Still wines 21% to 24%	$3.15 per gallon
Wines above 24%	Taxed as distilled spirits
Naturally sparkling wines	$3.40 per gallon
Artificially carbonated wines	$3.30 per gallon
Hard cider	$0.22 per gallon
Certain effervescent wines and mead under 8.5% ABV	$1.07 per gallon

[28] A barrel of beer is equal to 31 gallons.

[29] A proof gallon is the equivalent of one gallon of 50 percent alcohol spirits.

General Federal Tobacco Tax Rates

Product	General tax rate
Cigarettes (IRC 5701(b))	
Cigarettes generally[30]	$50.33 per 1,000
Large cigarettes	$105.69 per 1,000
Cigars (IRC 5701(a))	
Small cigars[31]	$50.33 per 1,000
Large cigars	Lesser of 52.75% of the sales price of 40.26 cents per cigar
Roll-your-own tobacco (IRC 5702(g))	$24.78 per pound
Pipe tobacco (IRC 5702(f))	2.8322 cents per pound
Smokeless tobacco (IRC 5702(e))	
Snuff	$1.51 per pound
Chewing tobacco	$50.33 per pound
Cigarette papers (IRC 5702(c))	3.15 cents per 50
Cigarette tubes (IRC 5702(d))	6.30 cents per 50

Reduced tax rates (or tax credits) may apply in the case of certain smaller production volumes for alcoholic beverage producers. For example, producers of distilled spirits may be eligible for a reduced tax rate of $2.70 per proof gallon on the first 100,000 proof gallons produced (rather than the standard $13.50 per proof gallon).[32] Similarly, certain small brewers may be eligible for a reduced rate of $3.50 on the first 60,000 barrels of beer and $16 per barrel on any remaining amount up to 2 million barrels (rather than the standard $18 per barrel).[33] Certain wineries may also be eligible for a small producer tax benefit, provided in the form of a tax credit. These rules generally limit the tax benefit only to products produced or substantially modified by the small producer, in order to limit the benefit received by large producers and to prevent a double-benefit.[34]

[30] Cigarettes are generally taxed as “small cigarettes” weighing not more than 3 pounds per thousand. Cigarettes exceeding this weight threshold are taxed as “large cigarettes.”

[31] Cigars weighing not more than 3 pounds per thousand are taxed as “small cigars.” Cigars exceeding this weight threshold are taxed as “large cigars.”

[32] IRC 5001(c).

[33] IRC 5051(a).

[34] See for example, IRC 5001(c)(5).

Because federal alcohol and tobacco taxes are generally levied on a per-unit or potency basis, it is not possible to determine a single percentage-based effective tax rate equivalent for any particular category of product. For example, if a 750 ml bottle of 100 proof whiskey is sold at wholesale for $8, the effective tax rate would be approximately 35 percent. However, if the same bottle contained higher-quality whiskey and sold at wholesale for $20 per bottle, the effective tax rate would be roughly 15 percent. The Congressional Research Services has provided some analysis on federal alcohol taxes, based on rough assumptions of a standard alcoholic beverage, finding that distilled spirits are taxed at approximately 21 cents per ounce of alcohol, compared to 8 cents for wine and 10 cents for beer.[35] In certain cases, particularly with respect to tobacco products, it is possible that the effective tax rate for federal excise taxes may exceed 100 percent.

Federal alcohol and tobacco taxes are generally paid semi-monthly.[36] Certain small alcohol producers may be eligible to pay taxes quarterly or annually.[37] Generally, an alcohol producer is subject to tax at the time that a product is "removed" from the producer's production facility and sold to a wholesaler.[38] Certain transfers between different production facilities may occur free of tax, provided the transferee assumes the tax liability of the transferor.[39] These "in-bond" transfers help to ensure that a product is taxed only once, even though the production process may involve multiple, separate, production facilities.

In certain limited cases, alcohol and tobacco may be exempt from tax.[40] Exported products are exempt from tax in the United States (but are normally taxed by the importing country). Alcohol may also be removed tax-free for use by a federal or state agency, for educational, scientific, or research purposes, or for use in certain non-beverage and manufacturing applications.[41] Alcohol that has been "denatured" and is therefore unfit for human consumption may also be removed tax-free.[42] If alcohol on which tax has been paid is subsequently used for certain tax-exempt purposes, a partial tax refund in the form of "excise tax drawback" may be allowed in certain cases.[43]

Background on Establishment and Permitting

The Federal Alcohol Administration Act (FAA Act) requires any person producing alcoholic beverages or selling alcoholic beverages at wholesale obtain a permit from the Treasury

[35] Sean Lowry, *Alcohol Excise Taxes: Current Law and Economic Analysis*, CRS Report R43350, December 23, 2015 (https://www.crs.gov/Reports/R43350).
[36] IRC 5061(d)(1), 5703(b)(2).
[37] IRC 5061(d)(4).
[38] See for example, IRC 5006(a)(1), 5213.
[39] See for example, IRC 5212.
[40] See for example, IRC 5704, 5214.
[41] See IRC 5003 for cross references relating to tax-free removals.
[42] IRC 5214, 5241.
[43] IRC 5111.

Department.[44] In addition, any person producing a taxable alcoholic beverage must register with the Treasury Department for tax purposes.[45] Federal food facility registration may also be required by FDA.

The Family Smoking Prevention and Tobacco Control Act requires manufacturers of tobacco products to register with the FDA.[46] Manufacturers of tobacco products must separately register with the Treasury Department for tax purposes.[47]

Generally, an alcohol or tobacco permit may be denied or revoked if the premises is inadequate to prevent tax evasion or diversion, operation of the premises do not comply with federal or state law, an applicant fails to disclose material information or makes a false statement, or the applicant lacks sufficient business experience or financial standing.[48] In addition, an alcohol permit application may be denied if the applicant has been convicted of a felony violation under federal or state law in the preceding five years, or a misdemeanor violation in the preceding three years related to alcohol. A tobacco permit application may be denied if the applicant has ever been convicted of a felony violation under federal or state law related to tobacco products.

Background on Regulation of Operations

Strict rules apply to the operations of tobacco and alcohol production facilities, intended to prevent tax evasion and smuggling. These rules include requirements for facility security,[49] rules regarding entry and inspection by government regulators,[50] and requirements for recordkeeping and reports.[51] In addition, manufacturers of alcohol and tobacco products may be required to maintain a surety bond, which serves to guarantee payment of excise tax liabilities in the case that the manufacturer fails to pay.[52] Certain small alcohol producers may be exempted from this requirement to obtain a bond, but must still comply with all other regulations regarding establishment, permitting, and operations.[53]

Similar rules apply to manufacturers of tobacco products, however no exceptions apply to the requirement to obtain bond.[54] In addition, manufacturers of tobacco products are required to annually pay a “special occupational tax” with respect to their tobacco production facilities.[55]

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[44] 27 USC 203.
[45] See for example, IRC 5171(c), 5172.
[46] 21 USC 387e.
[47] IRC 5712, 5713.
[48] See 27 USC 204 for alcohol permits and IRC 5712 for tobacco permits.
[49] See for example, IRC 5178, 27 CFR 19.192.
[50] See for example, IRC 5203, 27 CFR 19.11.
[51] See for example, IRC 5207, 27 CFR 19.571 *et seq.*
[52] IRC 5551, and see for example IRC 5173, 27 CFR 12.151 *et seq.*
[53] IRC 5551(d).
[54] See IRC Chapter 52, Subchapters B through E, IRC 5711 et seq.
[55] IRC 5731.

Proposal

Imposition of Tax on Cannabis Products

Section 5901 of the Internal Revenue Code, as added by Sec. 401 of the Discussion Draft would impose an excise tax on cannabis products in a manner similar to the tax imposed on alcohol and tobacco. The general rate of tax would be 10 percent for the year of enactment and the first full calendar year after enactment. The tax rate would increase annually to 15 percent, 20 percent, and 25 percent in the following years. Beginning in year five and thereafter, the tax would be levied on a per-ounce rate in the case of cannabis flower, or a per-milligram of THC rate in the case of any cannabis extract. The applicable rate for year five and thereafter would be a per-ounce or per-milligram of THC amount determined by the Secretary of the Treasury equal to 25 percent of the prevailing price of cannabis sold in the United States in the prior year.

In order to remove barriers to entry, small cannabis producers with less than $20 million in sales annually would be eligible for a 50 percent reduction in their tax rate, via a tax credit. Producers with more than $20 million in sales would be eligible for a tax credit on their first $20 million of cannabis sold annually, with sales above that amount subject to tax at the full rate. Similar to the reduced rates for alcohol producers, certain anti-abuse rules would limit the tax benefit only to products produced or substantially modified by the small producer, in order to limit the benefit received by large producers and to prevent a double-benefit.

Excise Tax Rates Proposed in Discussion Draft

Year	Top Rate	Rate on first $20 million in sales
Enactment	10%	5%
Year 1	10%	5%
Year 2	15%	7.5%
Year 3	20%	10%
Year 4	25%	12.5%
Year 5	25%*	12.5%*

** for year 5 and after the Secretary sets a rate based on quantity sold or milligram of THC in the case of a product other than flower. Rates are based on prevailing price of cannabis sold in the US in the prior year.*

Similar to current federal alcohol taxes, excise tax liability arises when the cannabis comes into existence; however, tax is determined and payable when cannabis products are imported or removed from the premises of a permitted cannabis producer. Cannabis products may be removed tax-free in the case of export, in-bond transfers, and research. Under the proposal, excise taxes must be paid semi-monthly by all cannabis producers.

The Sponsoring Offices request comment on cannabis excise tax provisions, including—

- The appropriate sales or production threshold for the small producer credit;
- Appropriate anti-double-benefit rules regarding the small producer credit, including rules related to substantial processing;
- The proper manner to measure potency of a cannabis product and which products should be subject to a per-THC content tax rather than a purely weight-based tax;
- The appropriate entity and methodology for measuring the prevailing price of cannabis for purposes of setting annual rates of tax;
- Whether certain small producers should be eligible for quarterly or annual tax payments, similar to the rules applicable to small alcohol producers;
- Considerations related to the non-application IRC 280E, including transition rules and interactions with tax incentives for activities that may have occurred while a business was subject to the limitation on credits and deduction;, and
- Additional conforming amendments to other parts of tax law, including the definition of tobacco rolling papers tubes and interactions with the alcohol and tobacco tax regimes.

Establishment and Permitting

Section 301 of Title 27, as added by Sec. 511 of the Discussion Draft would require any person selling cannabis products at wholesale to obtain a permit from the Treasury Department. In addition, any person producing taxable cannabis products must obtain a Treasury Department permit and register for tax purposes. A producer of cannabis products would also be required to register with the FDA. The Discussion Draft instructs the Treasury Department and FDA to coordinate in order to streamline the permitting process and minimize administrative duplication, and it is intended that a cannabis business would be able to make all three filings on a single, unified application.

The Discussion Draft provides that a cannabis permit may be denied or revoked if the premises is inadequate to prevent tax evasion or diversion, operation of the premises do not comply with federal or state law, or an applicant fails to disclose material information or makes a false statement. In addition, a cannabis permit application may be denied if the applicant has been convicted of a disqualifying offense. For these purposes, a disqualifying offense is a felony criminal offense that occurred after enactment of this Act and within the preceding three years

related to cannabis diversion or cannabis tax evasion. An applicant may apply to the Cannabis Products Advisory Committee for a waiver with respect to a disqualifying offense if the Committee finds that the applicant has established sufficient evidence of mitigation or rehabilitation and fitness to maintain cannabis operations in compliance with state and federal law.

The Discussion Draft provides a permitting transition rule that would allow a cannabis business to continue operations even if TTB hasn't yet approved their application, provided such person files a complete and accurate application with TTB within 90 days of the date on which TTB begins accepting applications, and complies with all applicable laws and regulations, including payment of required taxes. The Discussion Draft would also provide a permit fee waiver in the case of a first-time applicant with income below 250 percent of the Federal Poverty Level.

The Sponsoring Offices believe reducing barriers to entry is a crucial component of restorative justice. At the same time, allowing illegal operators to maintain a cannabis permit while repeatedly and intentionally violating the law does a disservice to those cannabis entrepreneurs that pay their taxes and comply with public health and public safety laws. The Sponsoring Offices request comment on establishment and permitting provisions, including—

- The appropriate balance to strike between reducing barriers to entry, while preventing illegal operations that may engage in cannabis diversion, tax evasion, or threaten public health and safety;
- Appropriate criteria for the waiver of a qualifying offense with respect to a permit application;
- Additional recommendations on streamlining the permitting and establishment process involving multiple government agencies; and
- The operation of the permitting transition rule for entities already in operation as well as those that may commence business shortly after enactment.

Operations

Sections 5911 through 5925 of the Internal Revenue Code, as added by Sec. 401 of the Discussion Draft would establish operational rules for manufacturers of cannabis products, similar to those for alcohol and tobacco. The Secretary of the Treasury would be authorized to enter facilities and inspect books and records of manufacturers of cannabis products, as well as require reporting and tax filing. Proprietors of cannabis manufacturing facilities would be required to maintain such facilities in a manner to prevent tax evasion or diversion. In addition, manufacturers of cannabis products are required to maintain a bond, to ensure cannabis excise taxes are paid.

The Sponsoring Offices request comment on provisions relating to the operations of cannabis production facilities, including whether certain small cannabis producers should be exempt from the requirement to maintain a bond, similar to the exception in current law for small alcohol producers.

PUBLIC HEALTH, CANNABIS ADMINISTRATION, AND TRADE PRACTICES

Background

Background on Food and Drug Administration Regulation

The Food and Drug Administration is responsible for protecting the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; and cosmetics are safe and properly labeled. FDA is also responsible for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and reduce tobacco use by minors.[56]

Under current law, the Federal Food, Drug, and Cosmetic Act (FFDCA) prohibits marketing of food and dietary supplements containing cannabis.[57] In addition, any substance, including cannabis, that is intended for use as a drug is subject to FDA drug approval requirements.[58] The term "drug" is broadly defined in the FFDCA to include, for example, any article intended to treat a disease or affect the structure or function of the body.[59] FDA drug approval requirements help protect patients from fraudulent health claims, maintain FDA's gold standard of safety and effectiveness of drug products, and incentivize drug research and development. Maintaining strong incentives for research and development of drugs containing cannabis is especially important, given both its potential promising health benefits and potential harmful effects. FDA has approved three cannabis-derived drugs and a fourth drug that contains cannabidiol (CBD). FDA has not approved any drug containing cannabis.[60]

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[56] 21 USC 393; https://www.fda.gov/about-fda/what-we-do.

[57] 21 USC 321(ff), (ll).

[58] 21 USC 355.

[59] 21 USC 321.

[60] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), Jan. 2021 (https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd).

Background on Alcohol and Tobacco Tax and Trade Bureau Regulation

The Federal Alcohol Administration Act[61] was enacted shortly after the ratification of the 21st Amendment, which ended alcohol prohibition in the United States. The FAA Act remains largely unchanged and operates as the cornerstone of federal alcohol regulation today. The FAA Act establishes requirements for producers, importers, and distributors of alcohol products to obtain a "basic permit" from the Treasury Department, as described earlier in this summary.[62] The various regulations and prohibitions in the FAA Act apply to those permitted entities.

The FAA Act vests authority to regulate alcoholic beverages with the Treasury Department, and the Alcohol and Tobacco Tax and Trade Bureau (TTB) within the Treasury Department is charged with a dual mandate to (1) "protect the revenue" through the collection of taxes and enforcement of tax laws; and (2) "protect the public" by preventing consumer misinformation, enforcing health and safety regulations, and preventing uncompetitive trade practices in the marketplace.[63] Congress vested this wide range of regulatory responsibilities within the Treasury Department in order to provide a single administrative authority for all tax and regulatory requirements.[64, 65]

The FAA Act prohibits unfair competition and unlawful practices, generally including (1) exclusive sale agreements meant to limit market competition; (2) commercial bribery or other monetary inducements meant to limit market competition; and (3) certain non-monetary inducements meant to limit market competition (such as the uncompensated use of business property or non-arms-length transactions).[66]

The law also prohibits misleading labeling and advertising practices.[67] To enforce the strict labeling requirements established under Treasury regulations, the FAA Act and underlying regulations require that the label of any alcohol product imported into the United States or sold in interstate commerce must be approved by the Treasury Department through a Certification of Label Approval (COLA) process. TTB-issued COLAs are posted on a publicly-accessible database, and states may require that an alcohol product have a valid COLA to be legally sold under state law.[68] TTB may deny a COLA if it determines a product has been mislabeled.

While TTB is the primary agency charged with administering requirements related to the labeling of ingredients and substances, TTB generally defers to the Food and Drug

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[61] 27 USC 201 *et seq.*

[62] 27 USC 203.

[63] About Us, Alcohol and Tobacco Tax and Trade Bureau Web site (https://www.ttb.gov/about-ttb).

[64] *Hearings before U.S. Senate Committee on Finance Subcommittee on H.R. 191 Relating to Taxes on Wines and H.R. 9185 An Act to Insure the Collection of the Revenue on Intoxicating Liquor, to Provide for the More Efficient and Economical Administration and Enforcement of the Laws Relating to the Taxation of Intoxicating Liquor and for Other Purposes*, U.S. Senate Committee on Finance, 74th Congress (2nd session), March 6, 1936. (https://www.finance.senate.gov/imo/media/doc/74HrgLiqour3.pdf).

[65] See discussion in John O'Neil, *Federal Activity in Alcoholic Beverage Control,* Law and Contemporary Problems, Autumn, 1940, P. 570-599 (https://www.jstor.org/stable/pdf/1189485.pdf?refreqid=excelsior%3A458e141c12ba8bb7806013c699268804).

[66] 27 USC 205.

[67] 27 USC 205(e), (f).

[68] COLA public registry available at: https://www.ttb.gov/labeling/cola-public-registry.

Administration (FDA) regarding requirements related to health and safety, including adulteration determinations under the Federal Food Drug and Cosmetic Act (FFDCA). Under the FFDCA, alcoholic beverages are regulated as food.[69] FDA has authority to take action with respect to adulterated food, including alcoholic beverages. Manufacturers of alcoholic beverages are subject to requirements for registration of food facilities and good manufacturing practice for foods.[70]

The FAA Act requirements concerning the labeling of ingredients and substances apply to distilled spirits, certain wines, and malt beverages only. Alcoholic beverages that are not covered by the labeling provisions of the FAA Act, such as certain beers that are not malt beverages, are subject to ingredient and other labeling requirements under the FFDCA.[71]

A Memorandum of Understanding (MOU) between the TTB's predecessor agency (ATF) and the Food and Drug Administration governs the relationship between the two agencies.[72] The MOU generally provides that TTB operates as the main contact point with industry members during the product approval process, but that TTB will defer to FDA's findings regarding health and safety. For example, TTB has stated in guidance that if FDA deems an alcohol product to be adulterated because it contains an unsafe food additive, TTB will treat such adulterated products as mislabeled for purposes of the FAA Act and deny a COLA.[73]

In addition to the COLA process, TTB may also require a producer of alcoholic products to submit a product formula for approval, which includes a description of the product's ingredients and production process.[74] This information is necessary for TTB's tax collection function, but may also provide information useful for various other TTB functions. In certain cases, an industry member may also be required to submit a product sample for TTB lab testing.

Proposal

General Provisions Regarding Agency Jurisdiction

As noted previously, Sec. 102 of the Discussion Draft would transfer primary agency jurisdiction over cannabis regulation from the DEA to FDA and TTB. The provision also directs the heads of such agencies to enter into a memorandum of understanding regarding their respective responsibilities.

Specifically, FDA would be recognized as the primary federal regulatory authority with respect to the manufacture and marketing of cannabis products, including requirements related to

[69] 21 USC 321(f).

[70] 21 CFR parts 1, 110.

[71] FDA Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration, Dec. 2014 (https://www.fda.gov/media/90473/download).

[72] Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms, MOU 225-88-2000, Nov. 20, 1987 (https://www.fda.gov/about-fda/domestic-mous/mou-225-88-2000).

[73] TTB Industry Circular 2010-8, Alcohol Beverages Containing Caffeine, Nov. 23, 2010 (https://www.ttb.gov/images/industry_circulars/archives/2010/10-08.html).

[74] See for example 27 CFR 25.55.

minimum national good manufacturing practice, product standards, registration and listing, and labeling information related to ingredients and directions for use. TTB would be recognized as the primary federal regulatory authority with respect to the taxation of cannabis products and trade practices of cannabis enterprises including the collection of federal excise taxes and enforcement of tax laws; tracking and tracing of cannabis products; and prohibitions on unfair competition and commercial bribery. The agencies would have dual jurisdiction related to certain aspects of cannabis product labeling and packaging, advertising, and other consumer information; however, the Discussion Draft would instruct agencies to coordinate and reduce duplication to the greatest extent practicable.

Food and Drug Administration Regulation of Cannabis

Section 501 of the Discussion Draft would add a new chapter to the FFDCA, Chapter XI, which would establish the Center for Cannabis Products in FDA. The Center for Cannabis Products would regulate the cannabis aspect of all products containing cannabis, except those products containing cannabis that make claims regarding the treatment or prevention of disease in humans or animals. Products containing cannabis that make such disease claims would be regulated as drugs by FDA's Center for Drug Evaluation and Research or Center for Veterinary Medicine and would be subject to FDA drug approval requirements.

Products containing cannabis, except drugs containing cannabis, would be referred to as "cannabis products." Food and cosmetics that contain cannabis would continue to be regulated as food and cosmetics by the Center for Food Safety and Applied Nutrition and would also be regulated as cannabis products by the Center for Cannabis Products.

Under the Discussion Draft, cannabis products would not be regulated as dietary supplements, but the Discussion Draft would authorize manufacturers of cannabis products to make claims about the benefits of their products in the same manner that manufacturers of dietary supplements do today. Specifically, manufacturers of cannabis products would be able to make "structure-function" claims — that is, claims that characterize the way a substance affects the normal structure or function of the body. As with dietary supplements, these structure-function claims would need to be supported by competent and reliable scientific evidence and accompanied by a statement on the label that advises: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Under Section 501 of the Discussion Draft, the Center for Cannabis Products would be responsible for establishing and implementing requirements related to cannabis products, including those related to establishment registration, product listing, good manufacturing practice, product standards, product labeling, and product distribution and recall. Cannabis products not in compliance with these requirements would be deemed adulterated or misbranded, as applicable. Section 502 would make it a violation of federal law to distribute a cannabis product that is adulterated or misbranded.

Section 1104 of Chapter XI of the FFDCA, added by the Discussion Draft, would require owners and operators of establishments that are engaged in the manufacture, preparation,

compounding, or processing of a cannabis product to register their establishments with FDA upon first engaging in such activities and annually thereafter. Registrants would also be required to provide FDA with a list of cannabis products produced at each establishment. The product list would need to be updated and provided to FDA before any new cannabis product could be introduced into commercial distribution. The product list would need to be accompanied by all consumer information and other labeling as well as a representative sampling of advertisements for such cannabis product. TTB would be granted access to registration and listing information received by FDA.

Section 1105 of Chapter XI, added by the Discussion Draft, would require FDA issue regulations pertaining to distribution of cannabis products and good manufacturing practice. Specifically, this section would establish a minimum age for the purchase of cannabis by requiring FDA to issue regulations to prevent the sale and distribution of cannabis products to individuals who are under the age of 21. This section would also require FDA issue regulations regarding good manufacturing practice requirements, including requirements related to planting, cultivation, growing, and harvesting of cannabis products. Additionally, FDA would be authorized to issue regulations to impose additional restrictions on the sale and distribution of cannabis products if it is determined that such restrictions are appropriate for the protection of public health. Similarly, sec. 1106 of Chapter XI would require FDA to adopt, by regulation, cannabis product standards that are appropriate for the protection public health.

Sec. 1107 of Chapter XI, added by the Discussion Draft, would provide for the mandatory recall of a cannabis product if FDA determines that such product would cause serious, adverse health consequences or death. This section outlines the requirements and procedures for a mandatory recall.

Section 1108 of Chapter XI, added by the Discussion Draft, would establish record keeping requirements for manufacturers and importers of cannabis products. These entities would also be required to provide information and make reports to FDA that are needed to protect public health and assure that cannabis products are not adulterated or misbranded.

Section 1109 of Chapter XI, added by the Discussion Draft, would prohibit electronic cannabis product delivery systems from containing natural or artificial flavors.

Section 1110 of Chapter XI, added by the Discussion Draft, would clarify that state and local governments and Indian tribes could enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to cannabis products that is in addition to, or more stringent than, requirements established by the FDA. This includes any law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of cannabis products by individuals of any age, information reporting to the state, or measures relating to fire safety standards for cannabis products.

Sec. 502 of the Discussion Draft would add the definition of “cannabis” and “cannabis product” to section 201 of the FFDCA. The term cannabis would mean all parts of the plant Cannabis sativa L., whether growing or not, including seeds, resin extracted from any part of such plant,

and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. The definition of cannabis would exclude hemp. The term “cannabis product” would mean any product made or derived from cannabis that is intended for consumption or applied to the body of man or other animals, including any component of such product, but would not include articles that meet the definition of a drug, which in the case of cannabis products, would be articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.

Sec. 502 of the Discussion Draft would make various conforming amendments to the FFDCA including the addition of several prohibited acts that are intended to prevent sale or distribution of cannabis products to any person younger than 21 years of age, prevent single transactions involving the sale of more than 10 ounces of cannabis, and prevent the sale of cannabis products that contain alcohol, caffeine, or nicotine. It would also be a prohibited act for a manufacturer or distributor of cannabis products to fail to notify the Attorney General and the Secretary of Treasury if they have knowledge of cannabis products used in illicit trade. The Discussion Draft would also establish FDA authority over cannabis products in intrastate commerce. Additionally, this section would subject cannabis product establishments to FDA’s inspection authority and extend import and export requirements of the FFDCA to cannabis products.

Sec. 503 of the Discussion Draft would establish a program to expedite the development and review of applications for drugs containing cannabis that are manufactured by a small businesses owned and controlled by socially and economically disadvantaged individuals that operate in the cannabis industry.

Sec. 505 of the Discussion Draft would create a legal pathway for cannabidiol (CBD) in dietary supplements. This section would amend the definition of “dietary supplement” to remove the prohibition on marketing CBD as a dietary supplement. Additionally, the section would deem dietary supplements to be adulterated if they contain more than a level of CBD per recommended daily serving set by the Secretary. Certain dietary supplements would be required to submit New Dietary Ingredient (NDI) notifications to FDA. Additionally, the section would clarify that FDA would have the ability to require safety-related labeling or packaging requirements if needed and give FDA the ability to take enforcement action against any noncompliant CBD-containing products that is inappropriately labeled as a dietary supplement. Furthermore, the section would provide FDA with more comprehensive enforcement tools over products marketed as dietary supplements that contain articles that the sponsor intends to continue excluding from the definition of dietary supplement, such as synthetic (i.e. non-hemp derived) cannabidiol. These tools would help ensure that firms do not avoid the new requirements by simply developing their products with synthetic CBD rather than hemp-derived CBD.

Sec. 506 of the Discussion Draft would amend the Poison Prevention Packaging Act to authorize the Consumer Product Safety Commission to issue regulations setting standards for special packaging of cannabis products.

The Sponsoring Offices request comment on whether some or all cannabis products should be required to undergo premarket review before marketing and, if so, which cannabis products and the evidentiary standards for any proposed premarket review pathways.

Establishment of Cannabis Products Regulatory Advisory Committee

Sec. 501 of the Discussion Draft would establish the Cannabis Products Regulatory Advisory Committee, which FDA would convene and consult before promulgating regulations.

The Sponsoring Offices have not specified responsibilities or membership of the Advisory Committee and request comments on—

- Criteria for Advisory Committee membership to ensure diverse viewpoints and policy priorities are properly represented;
- Roles and responsibilities of the Advisory Committee; and
- The role of the Advisory Committee in agency consultation, including the administrative and rulemaking process.

Cannabis Administration and Trade Practices Enforcement

Sec. 511 of the Discussion Draft would establish additional restrictions on the interstate commerce of cannabis products that fail to comply with certain restrictions on packaging and labeling intended to prevent non-competitive market competition. Specifically, the provision prohibits packaging and labeling of cannabis products that would deceive the consumer with respect to the quantity, quality, analyses, guarantees, or production process of such product. The provision also prohibits packages and labels that are disparaging of a competitor, obscene, or would lead the consumer to believe that the product is endorsed by any living person of public prominence or any organization including government entities.

Sec. 112(b) of the Discussion Draft would direct the Secretary of the Treasury to establish a federal track and trace regime for cannabis products to prevent diversion as well as federal and state tax evasion. The provision would require manufactures of cannabis products to place identifiable codes, designs, or devices on the label of cannabis products to monitor movements of such products between the point of production and sale. The provision would require certain cannabis enterprises other than retailers to maintain records related to cannabis transactions, which would be available for inspection by federal and state agencies. The provision also requires any manufacturer or distributor of cannabis products to notify the Attorney General if they have knowledge of diversion or tax evasion.

Section 304 of Title 27, as added by Sec. 511 of the Discussion Draft would impose prohibitions against commercial bribery and uncompetitive trade practices to cannabis, under rules similar to the rules that apply to alcohol products. Specifically, the provision would prohibit (1) exclusive sale agreements meant to limit market competition, (2) commercial bribery or other monetary inducements meant to limit market competition, and (3) certain non-monetary inducements meant to limit market competition. The provision would also prohibit misleading labeling and advertising practices. These rules are specifically intended to ensure that small and independent producers have fair access to the cannabis marketplace, and to prevent market concentration among a few, large firms.

Sec. 303 of Title 27, as added by Sec. 511 of the Discussion Draft would require the Secretary of the Treasury in consultation with other agencies to establish a process in regulation for the lawful delivery of hemp that inadvertently exceeds the permissible THC limitations for hemp to a permitted cannabis enterprise for the proper processing of such products. Additional provisions throughout the Discussion Draft conform rules related to the tax-free use of industrial non-beverage alcohol in the production and manufacturing processes of cannabis and hemp products. In addition, conforming rules provide for drawback of cannabis tax for products which have been processed to remove THC, including those that would qualify as hemp after such processing.

The Sponsoring Offices believe that robust enforcement against commercial bribery and uncompetitive practices is critical to ensure that small and independent cannabises have an equal footing in the marketplace. In addition, consistent labeling and disclosure rules serve to protect the public and prevent misleading practices by market participants. The Sponsoring Offices request comments on cannabis administration and trade practices enforcement, including—

- Ways to reduce compliance costs for small businesses while ensuring that market participants comply with necessary labeling and trade practice rules;
- Whether additional rules may be necessary to prevent uncompetitive practices, and the interactions with trade practice rules administered by other agencies, including the Federal Trade Commission;
- Transition rules to address cannabis products that already exist in the marketplace or those introduced in the marketplace, including before TTB and FDA issue regulations or other guidance;
- Design of the track and trace regime to prevent cannabis diversion while minimizing compliance burdens; and
- Whether and how a single federal track and trace regime could replace the various, complex, state-based seed-to-sale tracking systems.

COMPTROLLER GENERAL REVIEW AND MISC. PROVISIONS

The legacy of the War on Drugs runs deep within our laws and society. While the Discussion Draft aims to address these inequities in a comprehensive fashion, additional work will be required to fully uproot the discrimination in our legal system. Sec. 601 of the Discussion Draft instructs the Comptroller General to conduct a review of federal laws, regulations, and policies, to identify additional areas in need of change, including a study on replacing the term "marijuana" and "marihuana" with "cannabis" through the U.S. Code and regulations. The provision requires the Comptroller submit a report to Congress and relevant agencies within two years of enactment.

ADDITIONAL ISSUES AND GENERAL ITEMS

This Discussion Draft attempts to address a broad range of potential issues related to cannabis reform and restorative justice. However, the draft is not intended to limit discussion of any germane topic not specifically addressed in the draft. In addition, the draft is intentionally silent in a number of areas where comments are expressly requested.

The Sponsoring Offices request comment on additional, general, and unspecified items, including—

- The necessary funding levels and resources for agencies to carry out the purposes of this Act;
- The necessary amounts appropriated for grants to carry out the purposes of this Act;
- Consideration of transition rules and effective dates;
- Interactions with state and local laws;
- Interactions with international obligations and treaties;
- Interactions and additional considerations regarding hemp;
- Additional opportunities to expand restorative justice and access to capital for historically-disadvantaged entrepreneurs; and
- Any other areas of concern to stakeholders, federal agencies, members of Congress, and state and local regulators.