

19HR234M

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION



MEMORANDUM OF AGREEMENT

I. Background and Purpose

This Memorandum of Agreement (MOA) is between the Department of Justice, Drug Enforcement Administration (DEA), and Grower Name (Grower) who has applied for a DEA registration as a bulk manufacturer to supply to researchers of any (or all) of the following schedule I controlled substances: marihuana (7360); marihuana extract (7350); and tetrahydrocannabinols (THC) (7370) at Grower's Address, under DEA Document Control Number _____.

The Single Convention on Narcotic Drugs, 1954, (Single Convention), 18 U.S.T. 1407, requires the United States to purchase and take physical possession of marihuana crops and to control importation, exportation, and wholesale trading. DEA codified regulations at 21 C.F.R. Part 1318 to ensure DEA carries out these obligations. See 85 FR 82333-01 (Final Rule, Controls To Enhance the Cultivation of Marihuana for Research in the United States (2020)). These regulations also contain provisions and obligations for Grower, which extend beyond the Controlled Substance Act's (CSA) general requirements that registrants maintain records, make certain reports, and maintain effective controls against diversion (e.g., security).

This MOA's purpose is to outline the means by which DEA and Grower agree to carry out these necessary and important functions.

II. Authority

- (a) Single Convention on Narcotic Drugs, 1954, 18 U.S.T. 1407.
- (b) The Controlled Substances Act, 21 U.S.C. § 801 et seq.
- (c) DEA Regulations, 21 C.F.R. Chapter II.
- (d) DEA Final Rule, Controls To Enhance the Cultivation of Marihuana for Research in the United States, 85 FR 82333-01 (2020).

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III. Definition of Terms Used in This MOA

The definitions contained in the CSA at 21 U.S.C. § 802 and DEA regulations at 21 C.F.R. § 1318.02 are incorporated into this MOA. In addition, for purposes of this MOA, the term "manicured plant material" means the dried leaves, flowering tops, and seeds of marihuana that are deliverable to DEA within four months of harvest. (See 65 FR 69574-01). A DEA-registered researcher or manufacturer who has a bona fide supply agreement to purchase manicured plant material from Grower is identified herein as the "Buyer."

IV. Obtaining Bona Fide Supply Agreements and Requests for Quota

Individual Manufacturing Quotas (IMQ): On or before May 1 of the year preceding the year in which marihuana is to be grown, Grower will furnish an individual manufacturing quota (IMQ) application utilizing DEA Form 189. Initial applications as well as any adjustments in an IMQ may be filed electronically utilizing DEA's Quota Management System at

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<https://apps.deadiversion.usdoj.gov/webforms/app189Login.jsp>. For an IMQ to grow marihuana, Grower should express all quantities in terms of “manicured plant material.”

Grower also will include the following information with its request on an attachment to DEA Form 189:

- (a) The number of plants that are necessary to be grown in order to yield the requested amount of manicured plant material;
- (b) The expected moisture content of manicured plant material;
- (c) The anticipated yield of manicured plant material per plant;
- (d) Details about whether the marihuana will be grown from seeds and/or from cuttings;
- (e) Descriptions of all locations where marihuana will be grown, including whether those locations are indoor or outdoor; and
- (f) The anticipated length of the growing cycle.

If Grower does not anticipate commercial production but requires authority to grow marihuana to maintain a particular genetic strain or variety in anticipation of future plantings, then Grower shall submit an IMQ for that purpose. In these circumstances, all cuttings and biomass will be recorded, collected, and disposed of in accordance with Section XI.B of this MOA.

Grower will include in their IMQ application copies of documents that constitute the bona fide supply agreement(s) that justifies their quota application request. The bona fide supply agreement must include the name, address, and DEA registration number of the Buyer, along with the negotiated purchase price that the Buyer will pay along with the administrative fee to be paid to DEA. For purposes of calculating Grower’s IMQ, DEA will only consider bona fide supply agreements from existing DEA registrants.

If Grower enters into additional bona fide supply agreements after receiving its initial IMQ, Grower may apply for an adjustment to its IMQ for that calendar year, as provided in 21 U.S.C. § 826(e) and 21 C.F.R. §§ 1303.25(a) and 1303.27. DEA will calculate Grower’s IMQ in accordance with the requirements of 21 U.S.C. § 826 and 21 C.F.R. §§ 1303.25(b) and 1303.11. Grower shall communicate in writing (email preferred) any change in Buyers during the quota year, regardless of impact on Grower’s IMQ, to the Section Chief for the UN Reporting and Quota Section of DEA’s Diversion Control Division (UN Reporting and Quota Section).

If Grower produces marihuana in excess of its IMQ, Grower immediately will notify DEA of this event in writing (email preferred) to the Section Chief for the UN Reporting and Quota Section and the local DEA Office. These amounts shall be destroyed in accordance with Section XI.B of this MOA.

Grower may at any time abandon its right to manufacture all or any part of such quota by filing with the UN Reporting and Quota Section a written notice (email preferred) of such abandonment in accordance with the provisions of 21 C.F.R. § 1303.27. Grower will identify which Buyer’s bona fide supply agreement resulted in the request to abandon any portion of its IMQ. If DEA has collected payment and an administrative fee from the Buyer, DEA will return the negotiated rate payment back to the Buyer, but not the administrative fee paid to DEA.

Individual Procurement Quota (IPQ): On or before April 1 of the year preceding the year in which marihuana is to be grown, Grower will furnish an individual procurement quota (IPQ) application

utilizing DEA Form 250 identifying quantities of marihuana it intends to procure back from DEA for the purpose of producing marihuana extracts, marihuana preparations, or isolated chemical constituents. DEA will consider Grower's IPQ requests in establishing its IMQ.

V. Pruning, Culling, and Sampling

Grower may collect samples of marihuana and distribute them to DEA-registered analytical laboratories for chemical analysis during the pendency of cultivation and prior to DEA's taking possession of the marihuana grown. To limit the risk of diversion and keep the distribution within the legitimate purposes permitted by the CSA, the quantity of samples collected and distributed must be small and fully consumed during analytical testing. Grower will maintain records of the quantity sampled for testing purposes and the date of these transfers to DEA-registered analytical laboratories utilizing DEA Form 222.

Grower may prune plants or cull unwanted plants as it deems appropriate. All cuttings and biomass resulting from pruning and culling operations will be recorded using DEA Form 41, collected, and disposed of in accordance with Section XI.B of this MOA.

The amounts sampled and the amounts pruned will be excluded from Grower's total crop that DEA is required to purchase and possess. These quantities also will be excluded from Grower's IMQ.

VI. Harvest – Advance Notification, Harvest, Packaging, and Transfer of Ownership

Grower will provide DEA with 15-day advance written notification, via email to the Chief of the Regulatory Section of DEA's Diversion Control Division (Regulatory Section), of its intent to harvest marihuana. Grower will provide the date/time in which harvesting will begin. The quantity authorized to be harvested will not exceed Grower's IMQ.

DEA will only accept an appropriately packaged and labeled product. Grower will package and label the crop at Grower's expense in accordance with 21 C.F.R. Part 1302. Additionally, Grower will package the crop in containers consistent with the needs of Grower's Buyers, but each unit will not exceed 22.7 kilograms (50 pounds) in overall weight. The container will protect the product from contamination. Additionally, packaging will not impart a toxic or deleterious substance into the product. Each package will bear a label containing the following information:

- (a) the common or usual name of the product;
- (b) Grower's name, DEA registration number, address, and phone number;
- (c) Net quantity of contents (in grams or kilograms);
- (d) Batch and/or lot number; and
- (e) Percentage concentration of all marketed cannabinoids and terpenes.

Two DEA personnel will arrive at Grower's registered location to take physical possession of the crop. While DEA will make every effort to arrive on the day of harvest, DEA will take possession within four months of the harvest. DEA will take ownership of the crop by executing a DEA Form 222, expressing all quantities in kilograms. DEA will prepare DEA Form 222 and present it to an individual who is authorized to obtain and execute a DEA Form 222 on behalf of Grower. Grower will retain the original DEA Form 222 (as the supplier); DEA will retain a copy of the executed DEA Form 222 (as the purchaser). Execution of DEA Form 222 constitutes the transfer of ownership from Grower to DEA.

If Grower has grown marihuana for its own research and product development efforts, which may include the bulk manufacturing of marihuana extracts and highly purified cannabinoids and derivatives, and has obtained a procurement quota from DEA for that purpose, following execution of DEA Form 222 transferring ownership to DEA, Grower will execute a DEA Form 222. In this case, DEA will be the supplier, and Grower will be the purchaser. DEA will retain the original DEA Form 222 (as the supplier); Grower will retain a copy of the executed DEA Form 222 (as the purchaser).

If a Buyer(s) has not paid the negotiated purchase price and administrative fee to DEA at the time in which DEA and Grower are prepared to transfer ownership, then DEA will not accept title to that corresponding quantity of marihuana. If payment from the Buyer has not been received within four months of harvest, and if Grower fails to provide a substitute bona fide supply agreement from a new Buyer, DEA will direct Grower to destroy that corresponding quantity of marihuana.

VII. Storage of Marihuana on Behalf of DEA and Sampling for Analytical Testing

Grower will identify a secure location in the Grower's approved schedule I vault or safe where Grower will store marihuana owned by DEA on behalf of DEA. This schedule I vault or safe will be in a location where Grower has a DEA registration permitting Grower to store marihuana. DEA will have the right to access any schedule I vault or safe where any marihuana that it owns is stored by the Grower. Grower must demonstrate to DEA's satisfaction its ability to prevent the commingling of marihuana stocks maintained on behalf of DEA with stocks of marihuana that DEA subsequently distributed back to Grower pursuant to a DEA-issued procurement quota. Grower will employ safeguards to prevent diversion of marihuana owned by DEA.

DEA's Regulatory Section may authorize Grower in writing (to include email) to retrieve samples of marihuana in DEA's possession for the purpose of conducting chemical analysis.

VIII. Distributions of Marihuana from DEA's Stocks

DEA's Regulatory Section will authorize Grower in writing (to include email) to make distributions from DEA's stocks of marihuana to those Buyers who entered into bona fide supply agreements with Grower once DEA has confirmed that the Buyer has made payment to DEA for both the negotiated rate and the administrative fee. DEA will identify that particular batch or lot number, and the quantity, of the marihuana that will be removed.

Two of Grower's employees who have undergone criminal background checks as a condition of their employment will enter the secure storage area and remove the amount identified by DEA. Grower will record the amount removed and provide confirmation to DEA in writing (email preferred) to DEA's Regulatory Section. Grower shall bear the cost of shipping marihuana to the Buyer.

IX. Distributions of Marihuana, Marihuana Extracts, and Marihuana Resin from Grower's Existing Stocks

Grower will provide DEA with 15-day advance written notification (via email) of its intent to distribute marihuana, marihuana extracts (which do not meet the definition of a marihuana preparations), or marihuana resins from its existing inventory. Grower will provide this written email notification on company letterhead and include the name of the Buyer(s), their DEA registration number, and the quantity to be distributed.

DEA's Regulatory Section will provide a written authorization or objection to Grower's proposed distribution. Any DEA objection will be based on its conclusion that a proposed distribution is likely to be diverted or otherwise be in conflict with the CSA, or on the basis that a researcher, who is the intended recipient of the marihuana, has been issued an Immediate Suspension Order (ISO) or a final order revoking their DEA registration. In the event of written objection from DEA to the proposed distribution, Grower agrees not to make the proposed distribution.

This 15-day advance notification process does not apply to distributions of marihuana preparations (including marihuana extracts that contain alcohol or other non-cannabis-derived solvents) in Grower's possession.

X. Invoicing and Payment for Harvested Marihuana Transferred to DEA

When Grower provides its 15-day advance notification of its intent to harvest marihuana (see Section VI above), it will invoice DEA for the harvested marihuana it intends to sell to DEA. The invoice will state the quantity and negotiated price for each Buyer and the DEA Registration number of the Buyer with which Grower has a bona fide supply agreement. The quantity of marihuana on the invoice will not exceed Grower's IMQ. The Grower will send the invoice to the Registration and Program Support Section of DEA's Diversion Control Division (Registration and Program Support Section).

DEA will pay Grower within 30 days of taking ownership of the crop. DEA and Grower will arrange for payment via Electronic Fund Transfer.

XI. Other General Terms

- A. Security: Grower will ensure compliance with the security requirements set forth in 21 C.F.R. §§ 1301.71, 1301.72, 1301.73, and 1301.74.
- B. Destruction of Controlled Substances: Grower will dispose of controlled substances in accordance with 21 C.F.R. § 1317.05(a)(4)(ii)(C) or 21 C.F.R. § 1317.05(b) and in compliance with applicable federal and state environmental laws. If Grower has an appropriate secure space on its premises, and if permissible under state and local law, Grower may also set fire to marihuana plants and plant parts piled in the secured field (burning) or may create a trench deep enough to cover marihuana plants and plant parts with 12 inches of soil (deep burial). These additional disposal methods may only occur in the presence of an agent of the DEA or other authorized DEA personnel.
- C. Reporting and Recordkeeping: Grower will establish and maintain controls consistent with the inventory, recordkeeping, and reporting requirements found under the CSA and DEA's implementing regulations. Grower will maintain inventories, records, and/or any other reports, as specified under 21 U.S.C. § 827 and 21 C.F.R. § 1304, for a period of at least two years. These records will be readily retrievable (as defined in 21 C.F.R. § 1300.01) upon request for inspection by DEA. Grower agrees to cooperate and permit DEA to inspect and copy such inventories, records, and reports requested without the need of an Administrative Inspection Warrant and to make employees available for interviews by DEA.

Within 30 days after the harvest, Grower will report the total amount of material manufactured, expressed as manicured plant material to the Section Chief for the UN Reporting and Quota

Section. DEA may require additional quarterly or annual reports to fulfill quota obligations and/or reporting obligations to the United Nations International Narcotics Control Board.

By January 31, Grower will submit inventory, acquisition, and disposition data to DEA for the preceding calendar year utilizing DEA’s Year End Reports Online system at <https://apps.deadiversion.usdoj.gov/webforms/app189Login.jsp>. This system is also the supporting platform for the Quota Management System through which Grower will submit new and revised quota applications for marihuana, marihuana extract, and THC.

- D. Inventory Records: Each inventory will be a physical count of all controlled substances on hand on the date the inventory is taken, and Grower will maintain the inventory in written, typewritten, or printed form at the registered location. Each inventory will include all information listed in 21 C.F.R. § 1304.11.

- E. Automation of Reports and Consolidated Orders System (ARCOS): Grower will adhere to the reporting requirement of 21 U.S.C. § 827(d)(1) and 21 C.F.R. § 1304.33, any newly implemented ARCOS requirements, and the requirements of 21 C.F.R. Part 1305.

- F. Theft and Loss Reporting: Grower will notify the Local Diversion Field Office and DEA’s Regulatory Section, in writing (email preferred), of any theft or loss of marihuana, including a theft or loss of marihuana owned by DEA, within 24 hours of discovery of the theft or loss. Grower also will report all in-transit losses of marihuana by their agent, or the common or contract carrier selected for distribution activities, within one business day of discovery of such theft or loss. Grower also will complete and submit to the Local Diversion Field Office in his or her area a DEA Form 106 regarding the theft or loss.

XII. Correspondence with DEA Headquarters Personnel

Direct written communications to DEA’s headquarters elements who are referred to in this MOA should be directed to the email (preferred) and postal addresses below:

DEA Headquarters Element	Email Address	Postal Address
Regulatory Section	DRGMJGrowerProgram@dea.gov	Drug Enforcement Administration Regulatory Section/DRG Attention: Marihuana Growers Program 8701 Morrissette Drive Springfield, VA 22152
Registration and Program Support Section	DRRO@dea.gov	Drug Enforcement Administration Registration Section/DRRO Attention: Marihuana Growers Program P.O. Box 2639 Springfield, VA 22152-2639

UN Reporting and Quota Section	DEAQuotas@dea.gov	Drug Enforcement Administration UN Reporting and Quota Section/DRQ Attention: Marihuana Growers Program 8701 Morrissette Drive Springfield, VA 22152
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XIII. Non-Liability of Drug Enforcement Administration

The United States assumes no liability with respect to the performance of any contractual terms agreed to by Grower and a Buyer of bulk marihuana, including but not limited to the quantity or quality of any marihuana delivered to a Buyer. If a Buyer deems the delivered marihuana to be defective, the Buyer's sole remedy for damages will be against Grower and not the United States.

XIV. Duration, Amendment, and Effect

- A. Execution: This MOA may be executed in counterparts, each of which constitutes an original, and all of which constitute one and the same agreement. Copies or facsimiles of signatures will constitute acceptable, binding signatures for purposes of this MOA. This MOA is effective and becomes binding upon the date of the last signature below. Each person who signs this MOA in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this MOA in their official capacities.

- B. Automatic Renewal: Unless terminated for cause by DEA, this MOA is effective for a one-year initial term from its effective date, subject to automatic renewal for up to four additional one-year terms.
 - 1. If, at the time the initial term or a renewal is set to expire, the Grower has submitted a renewal application that is still being processed by the DEA at the end of a one-year term and is allowed to continue to operate on a day-by-day basis until the registration is renewed in accordance with 21 C.F.R. § 1301.36(i), the term set to expire will be automatically extended until the registration is renewed.

 - 2. This MOA will automatically renew for an additional one year term upon DEA's approval of Grower's application for renewal of its registration as a bulk manufacturer of marihuana, marihuana extract, and THC unless, on or before 60 days before the expiration of the current term, either party provides written email notice of its intention not to renew.

 - 3. This MOA will terminate at the end of the fourth renewal term or the end of a one-year term that is not renewed.

- C. Termination for Cause: DEA may unilaterally terminate this MOA at any time for cause without prior notice by issuing an ISO pursuant to 21 U.S.C. § 824(d) against Grower's registration as governed under this MOA, or by issuing an Order to Show Cause as to which a final decision is reached by DEA to suspend or revoke Grower's registration as governed under this MOA.

- D. Severability: In the event that any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this MOA, but this MOA shall be construed as if such invalid, illegal, or unenforceable provision had never been contained herein.
- E. Modification: This MOA constitutes the full and complete agreement between the Parties. No other promises or agreements will be binding unless placed in writing and signed by both Parties. All material representations, understandings, and promises of the Parties are contained in this MOA, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this MOA, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this MOA or to the consummation of the transactions contemplated by this MOA. This MOA may be revised at any time with, and only with, the mutual written consent of the Parties. Modifications to the MOA will become effective on the date of the last signature of the authorized representatives of each Party.

XIV. Additional Terms and Conditions

- A. Compliance with State and Local Laws: Any bulk manufacturing, growing, cultivation, harvesting, disposal, or distribution of marihuana must be lawful in the state and locality where such action takes place. Such action also must be in compliance with any and all applicable state and local laws, statutes, and regulations, and otherwise permitted by all applicable state and local regulatory and law enforcement agencies. Failure to be in such compliance can constitute grounds for administrative action.

Grower shall immediately notify DEA of any change in their authorization from the state or the U.S. Food and Drug Administration to engage in the manufacture of marihuana, and any violations of other federal, state, and/or local laws related to controlled substances. Failure to immediately notify DEA of any such event can constitute grounds for administrative action.

- B. Freedom of Information Act: In the event of potential Freedom of Information Act requests, Grower and DEA consent that each may disclose this MOA, and information about said MOA, to the public.
- C. Good Faith: The terms and provisions of this MOA shall be executed in good faith.
- D. Venue & Jurisdiction: The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this MOA shall be in any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act, as amended.
- E. Costs: Each Party to this MOA shall bear his or its own legal and other costs incurred in connection with this matter, including in the preparation and performance of this MOA.

FOR GROWER:

Name, Title, Name of Company

Date: _____

Name, Title, Name of Company or
Attorney Firm

Date: _____

Name, Title, Name of Company or
Attorney Firm

Date: _____

Note: The DI will adjust Grower's signature block to include the proper Grower signatories. Two or more signatories are required for Grower.

FOR DRUG ENFORCEMENT ADMINISTRATION:

Special Agent In Charge, Office, Division

Date: _____

Diversion Program Manager, Office, Division

Date: _____