INDUSTRIAL HEMP ENROLLMENT AND OVERSIGHT (IHEO) AUTHORIZATION FOR INHALABLE PRODUCTS MANUFACTURERS

Incomplete applications will be returned. See Page 3 for Instructions.

☐ **NEW APPLICANT** ☐ **RENEWAL APPLICANT** IHEO Authorization Number (if not new): _____

☐ **OWNERSHIP CHANGE** ☐ **RELOCATION**—Previous Address: _____

Do you manufacture your own extract? ◯ Yes ◯ No

1. Name of Firm			6. Mailing Address (if different or P.O. Box number)		
2. DBA (Use other sheets as needed)			7. Mailing Address (continued)		
3. Facility Address (number, street)			8. City	State	ZIP Code
4. Facility Address (continued)			9. Country (if other than United States)		
5. City	State	ZIP Code	10. Website (URL)		

11. Type of Ownership ☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation ☐ Limited Liability Company ☐ Nonprofit ☐ Other: _____

12. Owner's Name / Corporate Name (if applicable)	State of Incorporation or State of Tax Filing
13. Owners', Officers' and Board Members' Names and Titles	Owners', Officers' and Board Members' Names and Titles

14. List all current and proposed industrial hemp sources. Attach documents showing hemp source is an approved source.

Business Name of Industrial Hemp Source (Must be Approved Source)	Business Address of Industrial Hemp Source	Registration/License Number of Industrial Hemp Source	Name of Entity that Issued the Registration/License

15. Commodities/Products: Check all inhalable products containing industrial hemp that are manufactured, packed or held at your facility. (Check all that apply.) Attach up to three product labels.
☐ Vape Cartridges ☐ E-Liquid Vials ☐ Pod/Capsule ☐ Other:

Continue to Next Page

16. Industrial Hemp Enrollment and Oversight (IHEO) Authorization Fee:

Tier	Check Which Applies	Gross Annual Revenue	Inhalable Product IHEO Authorization Fee	Tier	Check Which Applies	Gross Annual Revenue	Inhalable Product IHEO Authorization Fee
1	☐	Less than or equal to $100,000	$1,700	6	☐	$5,000,001 to $7,500,000	$5,700
2	☐	$100,001 to $500,000	$2,600	7	☐	$7,500,001 to $12,500,000	$6,800
3	☐	$500,001 to $1,500,000	$3,300	8	☐	$12,500,001 to $17,500,000	$8,100
4	☐	$1,500,001 to $3,000,000	$4,000	9	☐	$17,500,001 to $25,000,000	$9,700
5	☐	$3,000,001 to $5,000,000	$4,800	10	☐	More than $25,000,000	$12,000

17. IHEO Authorization Fee: $

MAKE CHECKS PAYABLE TO: CA DEPARTMENT OF PUBLIC HEALTH (See Page 4 for Mailing Address)

The Food and Drug Branch (FDB) **MUST BE NOTIFIED IMMEDIATELY** of any changes in the above information as provided by applicable laws under CA Health and Safety Code Division 104, Parts 5 and 6 (Sherman Law). Under penalty of perjury, I declare that the information included with this application and all attachments are true, correct, and complete. Misrepresentations or omissions may be grounds for denial, revocation or suspension. I give permission for the below authorized representatives and/or signatories to speak about the application with CDPH.

18. Owner's Signature	Owner's Printed Name	Title OWNER/	Date

Authorized representatives and/or signatories:

19. Business Operator Name	20. Telephone Number	21. Emergency Number	22. E-Mail Address
23. Correspondent Name	24. Telephone Number	25. Alternate Phone #	26. E-mail Address

-End of Application-

Please note: All boxes must be completed. Incomplete applications will be returned.

Do Not Write Below This Line

IHEO Authorization #	Expiration Date	Date Received	Payment Type	Amount $

Instructions for Completing the Industrial Hemp Enrollment and Oversight (IHEO) Authorization for Inhalable Products Manufacturers

New Applicant/Renewal Applicant: Place an (X) in the box next to New Applicant if your firm has not previously applied for an IHEO authorization for inhalable products at this location while under the current ownership. Place an (X) in the box next to Renewal Applicant if your firm has already obtained an IHEO authorization for inhalable products for this location and you are renewing that authorization. If this firm has changed location or ownership, please submit a new application for IHEO authorization for the facility.

Do you manufacture your own extract: Place an (X) in the box next to Yes if your firm manufactures its own extract. If yes, you also must register as an extract manufacturer. Place an (X) in the box next to No if your firm does not manufacture its own extract.

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for licensure.
2. **DBA:** Enter any other name(s) your company is doing business as.

3.–5. **Facility Address:** Enter the number, street, city, state, and ZIP code for this facility location.

6.–8. **Mailing Address:** Enter the full mailing address if different from the facility address or P.O. Box.

9. **Country:** Enter the country where your facility is located if outside of the United States.
10. **Website:** Enter the website address for your business if applicable.
11. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
12. **Owner's Name/Corporate Name:** Enter the owner's name here or (if applicable) the name of the corporation. **State of Incorporation or State of Tax Filing:** Enter the state where the firm is incorporated. If not incorporated, enter the state where the firm files taxes.
13. **Owners' and Officers' and Board Members' Names and Titles:** List the business owners' and officers' and board members' names and titles.
14. **List Industrial Hemp Sources:** List all current and proposed industrial hemp sources used for manufacturing. Attach additional pages if you have more than three sources. Attach documents showing industrial hemp is an approved source.
15. **Commodities/Products:** Check all inhalable products containing industrial hemp that are manufactured, packed or held at your facility. Attach three product labels. If there are fewer than three products, attach all product labels. You may attach a copy or the actual label. If you are only holding the product as a warehouser, you do not need to attach labels.
16. **Industrial Hemp Enrollment and Oversight (IHEO) Authorization Fee**: First, determine your current or estimated gross annual revenue of industrial hemp inhalable products. Next, check the corresponding tier that applies and enter the total into Question 17.
17. **IHEO Authorization Fee:** Enter the amount due. Send this amount with your completed application to the address listed.
18. **Owner's Signature, Printed Name, Title, Date:** This section **must** be signed by the majority owner of the business to authorize not only the application, but the representatives and/or signatories whom they authorize to speak on behalf of the firm.
19. **Business Operator:** Enter the full name of the person who manages the operations of your business and their title.
20. **Business Telephone Number:** Enter the daytime business telephone number for your business.
21. **24-Hour Emergency Contact Number:** Enter the phone number where the firm may be reached in the event of an emergency.

22. **Business Operator E-mail Address**: Enter the e-mail address of the business operator, or the main company e-mail box.
23. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
24. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
25. **Correspondent Alternate Phone #:** Enter the correspondent's alternate number or another number that can be called for information.
26. **Correspondent E-mail Address:** Enter the facility e-mail address.

Please make all checks payable to: **CA Department of Public Health** Mail Application and checks to:			
Regular Mail:	California Department of Public Health Food and Drug Branch – Cashier MS 7602 P.O. Box 997435 Sacramento, CA 95899-7435	Overnight Mail:	California Department of Public Health Food and Drug Branch – Cashier 1500 Capitol Avenue, MS-7602 Sacramento, CA 95814

Call the Food and Drug Branch at (800) 495-3232 if you have additional questions about this application.

Firm Name: **Phone Number:**

Address:

Industrial Hemp Self-Attestation

Must be submitted with appropriate applications

Instructions

The owner must do the following:

- **a)** Initial section A, which applies to all industrial hemp products.
- **b)** Do you manufacture extracts? If yes, initial section B and complete section G.
- **c)** Is your commodity a human food product (food, dietary supplements, beverages, canned food products)? If yes, initial C and complete section G.
- **d)** Is your commodity a processed pet food? If yes, initial section D and complete section G.
- **e)** Is your commodity a cosmetic (topicals, beauty products, patches, and pet topicals and pet oils)? If yes, initial section E and complete section G**.**
- **f)** Is your commodity an inhalable product? If yes, initial section F and complete section G.

A. ALL INDUSTRIAL HEMP PRODUCTS

1. Products and Manufacturing

- **a)** The products do not contain cannabinoids produced through chemical synthesis. HSC 111920(f).
- **b)** The final form hemp product does not contain THC isolate as an ingredient. HSC 111920(g)(1)(B)(iii).
- **c)** The industrial hemp product was produced from industrial hemp grown in compliance with Division 24 (commencing with Section 81000) of the Food and Agriculture Code if sourced from within California or licensed in accordance with United States Department of Agriculture requirements if sourced from outside the state. HSC 111921(b).
- **d)** The products are not medical devices or prescription drugs or non-prescription drugs. HSC 111921.5(a)(1), HSC 111921.5(a)(2).
- **e)** The products do not contain nicotine or tobacco, and the products are not alcoholic beverages. HSC 111921.5(a)(3), HSC 111921.5(a)(4).
- **f)** Manufacturing is in a commercial location. 17 CCR 23210(b).
- **g)** The extract in the products came from a firm registered by the Department. 17 CCR 23200(b)(4), 17 CCR 23200 (c)(4), 17 CCR 23200 (d)(4), 17 CCR 23200 (e)(3).

(initials)

2. Certificate of Analysis (COA)

a) Each required COA will be truthful and accurate.

b) Each required COA will be from an independent testing laboratory that confirms the mass of the industrial hemp extract used in the final form product does not exceed a THC concentration of 0.3%, which includes but is not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC. HSC 111921(a)(1), HSC 111920(l).

(initials)

3. Independent Testing Laboratory

a) The testing laboratory does not have a direct or indirect interest in the entity for which testing is being done. HSC 111920(e)(1).

b) The testing laboratory does not have a direct or indirect interest in a facility that cultivates, processes, distributes, dispenses, or sells raw hemp products in this state or in another jurisdiction. HSC 111920(e)(2).

c) The testing laboratory does not have a license from the California Department of Cannabis Control for anything other than as a licensed testing laboratory. HSC 111920(e)(3).

d) The testing laboratory is compliant with one of the following:

- Licensed by the California Department of Cannabis Control. HSC 111920(e)(4)(A).
- ISO 17025 accredited. HSC 111920(e)(4)(B).

(initials)

4. Testing

a) The raw extract final form was tested by an independent testing laboratory, to allow its use as an ingredient prior to being incorporated into a product. HSC 111925(a)(1), HSC 111925(a)(2).

b) The final form product has a total THC concentration, including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC, that does not exceed 0.3%, per testing by an independent testing laboratory. HSC 111925(a)(3), HSC 111920(l).

(initials)

5. Labeling and Advertisement

a) There is no health-related statement that is untrue on the label of the products or published or disseminated in advertising or marketing. HSC 110407.

b) Advertising and marketing do not directly target children or persons who are pregnant or breastfeeding. HSC 111926(b).

c) Advertising or marketing placed in broadcast, cable, radio, print, or digital communications is only displayed where at least 70% of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data. HSC 111926(c).

(initials)

B. EXTRACT MANUFACTURERS

1. Products are manufactured pursuant to good manufacturing practices. HSC 111922.3(a).
2. The extract in its final form (ready to be included as an ingredient) has a total THC concentration, including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC, that does not exceed 0.3%, per testing by an independent testing laboratory. HSC 111925(a)(3), HSC 111920(l).
3. The raw hemp product has a certificate of analysis from an independent testing laboratory that confirms the raw hemp product is the product of a batch of industrial hemp that was tested by the independent testing laboratory. HSC 111952.2(a).
4. The raw hemp product has a certificate of analysis from an independent testing laboratory that confirms that a tested representative sample of the batch of industrial hemp contained a total THC concentration, including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC, that does not exceed 0.3% on a dry-weight basis. HSC 111952.2(b), HSC 111920(l).
5. The raw hemp product has a certificate of analysis from an independent testing laboratory that confirms that the tested sample of the batch did not contain contaminants that are unsafe for human or animal consumption. HSC 111952.2(c).
6. The raw hemp product complies with the same contaminant levels as those for cannabis. HSC 111925.4(a).

(initials)

C. HUMAN FOOD (Food, Dietary Supplements, Beverages, and Canned Food Products)

1. The food products were manufactured in compliance with good manufacturing practices. HSC 110469(a), 111922.3(a).
2. All parts of the hemp plant used in food products come from a state or country that has an established and approved industrial hemp program that inspects or regulates hemp under a food safety program or equivalent criteria. HSC 110469(b)(1).
3. The industrial hemp cultivator or grower is in good standing and in compliance with the governing laws of the state or country of origin. HSC 110469(b)(2).

4. The COA from an independent testing laboratory confirms the industrial hemp product was tested for any hemp derivatives identified on the product label or in associated advertising. HSC 111921(a)(2).
5. Food and beverage products are prepackaged and shelf stable. HSC 111922(b).
6. Packaging and labeling on the products include a label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the final form product batch by an independent testing laboratory. HSC 111926.2(a)(1).
7. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes all of the following:
    - The product name. HSC 111926.2(a)(1)(A).
    - The name of the product's manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.2(a)(1)(B).
    - The batch number, which matches the batch number on the product. HSC 111926.2(a)(1)(C).
    - The concentration of cannabinoids presents in the product batch, including, at a minimum, total THC (including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC) and any marketed cannabinoids or ingredient. HSC 111926.2(a)(1)(D), HSC 111920(l).
    - The levels within the product batch of contaminants. HSC 111926.2(a)(1)(E).
8. Packaging and labeling on the products include the product expiration or best by date, if applicable. HSC 111926.2(a)(2).
9. Packaging and labeling on the products include a statement indicating that children or those who are pregnant or breastfeeding should avoid using the product prior to consulting with a health care professional about its safety. HSC 111926.2(a)(3).
10. Packaging and labeling on the products include a statement that products containing cannabinoids should be kept out of reach of children. HSC 111926.2(a)(4).
11. Packaging and labeling on the products include the following statement: "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY." HSC 111926.2(a)(5).

(initials)

D. PROCESSED PET FOOD

1. Products are prepackaged and shelf stable. HSC 111922(b).
2. Products are manufactured pursuant to good manufacturing practices. HSC 111922.3(b).
3. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes all of the following:
    - The product name. HSC 111926.2(a)(1)(A).
    - The name of the product's manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.2(a)(1)(B).

- The batch number, which matches the batch number on the product. HSC 111926.2(a)(1)(C).
- The concentration of cannabinoids presents in the product batch, including, at a minimum, total THC (including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC) and any marketed cannabinoids or ingredient. HSC 111926.2(a)(1)(D), HSC 111920(l).
- The levels within the product batch of contaminants. HSC 111926.2(a)(1)(E).

(initials)

E. COSMETICS

1. Packaging and labeling on the products include a label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the final form extract or the final form product batch by an independent testing laboratory. HSC 111926.3(a)(1).
2. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes all of the following:
   - The product name. HSC 111926.3(a)(1)(A).
   - The name of the product's manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.3(a)(1)(B).
   - The batch number, which matches the batch number on the product. HSC 111926.3(a)(1)(C).
   - The concentration of cannabinoids presents in the product batch, including, at a minimum, total THC (including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC) and any marketed cannabinoids. HSC 111926.3(a)(1)(D), HSC 111920(l).
   - The levels within the product batch of contaminants. HSC 111926.3(a)(1)(E).
3. Packaging and labeling on the products include the product expiration or best by date, if applicable. HSC 111926.3(a)(2).
4. Packaging and labeling on the products include the following statement: "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY." HSC 111926.3(a)(3).

(initials)

F. INHALABLE PRODUCTS

1. The inhalable products manufactured are for the sole purpose of sale in other states. HSC 111921.6(a).
2. Inhalable products are not sold to consumers under 21 years of age. HSC 111929.
3. Inhalable products do not contain flavorings other than natural terpenes. HSC 111929.2(a).

4. Inhalable products do not contain polyethylene glycol (PEG). HSC 111929.2(b).
5. Inhalable products do not contain vitamin E acetate. HSC 111929.2(c).
6. Inhalable products do not contain medium chain triglycerides (MCT oil). HSC 111929.2(d).
7. Inhalable products do not contain squalene or squalene. HSC 111929.2(e).

(initials)

G. OWNER'S VERIFICATION SIGNATURE

Under penalty of perjury, I declare that the information included with this application and all attachments are true, correct, and complete. Misrepresentations or omissions may be grounds for denial, suspension, or revocation of CDPH registration/licensure and may be subject to other penalties.

If I am an out-of-state manufacturer, I consent to applicable laws under Sherman Law for the products of manufacture of this application. I also consent to inspections including but not limited to manufacturing, holding, and distributing sites, records, etc. by authorized agents of CDPH. I acknowledge that refusal to submit to inspection and commission of violations under Sherman Law may be grounds for denial, suspension or revocation of CDPH registration/licensure and may be subject to other penalties.

Owner's Signature: Title:

Owner's Printed Name: Date: