INDUSTRIAL HEMP ENROLLMENT AND OVERSIGHT (IHEO) AUTHORIZATION FOR COSMETICS MANUFACTURERS

Incomplete applications will be returned.

Do you manufacture your own extract? ◯ Yes ◯ No

1. List all current and proposed industrial hemp sources. Attach documents showing industrial hemp 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

2. List all products containing industrial hemp that are manufactured, packed or held at the facility. (Attach additional pages if necessary.) Attach up to three product labels.

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

Tier	Check Which Applies	Gross Annual Revenue	Cosmetics IHEO Authorization Fee	Tier	Check Which Applies	Gross Annual Revenue	Cosmetics IHEO Authorization Fee
1	☐	Less than or equal to $100,000	$1,600	6	☐	$5,000,001 to $7,500,000	$5,200
2	☐	$100,001 to $500,000	$2,400	7	☐	$7,500,001 to $12,500,000	$6,200
3	☐	$500,001 to $1,500,000	$3,000	8	☐	$12,500,001 to $17,500,000	$7,400
4	☐	$1,500,001 to $3,000,000	$3,600	9	☐	$17,500,001 to $25,000,000	$8,800
5	☐	$3,000,001 to $5,000,000	$4,300	10	☐	More than $25,000,000	$10,500

4. Cosmetics IHEO Authorization Fee: $ *(to be transferred to Question 18 on CDPH 8678.)*

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.

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

Authorized representatives and/or signatories:

6. Business Operator Name	7. Telephone Number	8. Emergency Number	9. E-Mail Address
10. Correspondent Name	11. Telephone Number	12. Alternate Phone #	13. E-mail Address

-End of Application-

Note: All boxes must be completed. Incomplete applications will be returned.

Do Not Write Below This Line

License Number	Expiration Date	Date Received	Payment Type	Amount

INSTRUCTIONS FOR COMPLETING THE INDUSTRIAL HEMP ENROLLMENT AND OVERSIGHT (IHEO) AUTHORIZATION FOR COSMETICS MANUFACTURERS

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. **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.
2. **List Products Containing Industrial Hemp:** List all cosmetics products containing industrial hemp that are manufactured, packed or held at your facility. Use additional sheets if necessary. 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.
3. **Industrial Hemp Enrollment and Oversight (IHEO) Authorization Fee:** First, determine your current or estimated gross annual revenue of industrial hemp cosmetics. Next, check the corresponding tier that applies. Finally, transfer the fee amount to Question 4.
4. **Cosmetics IHEO Authorization Fee:** Enter the amount, and transfer this amount to the CDPH 8678 form, Question 18.
5. **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.
6. **Business Operator:** Enter the full name of the person who manages the operations of your business and their title.
7. **Business Telephone Number:** Enter the daytime business telephone number for your business.
8. **24-Hour Emergency Contact Number:** Enter the phone number where the firm may be reached in the event of an emergency.
9. **Business Operator E-mail Address**: Enter the e-mail address of the business operator, or the main company e-mail box.
10. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
11. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
12. **Correspondent Alternate Phone #:** Enter the correspondent's alternate number or another number that can be called for information.
13. **Correspondent E-mail Address:** Enter the facility e-mail address.

Please ensure you sign this form and attach it along with the CDPH 8678 and associated payment. Please follow the instructions on the CDPH 8678 to remit payment to the California Department of Public Health.

Applicant Attestation – Industrial Hemp

Instructions

I. The owner must verify by adding initials on each line as follows:

(1) Complete Section A "**All INDUSTRIAL HEMP PRODUCTS"** section.

(2) Complete all applicable Sections (B through F) for every Industrial Hemp Product Types manufactured.

II. The owner must sign and complete verification in Section G at the end of the form.

A. ALL INDUSTRIAL HEMP PRODUCTS

1. **Products and Manufacturing**
   a) The products do not contain cannabinoids produced through chemical synthesis. HSC 111920(f). _____**(initials)**
   b) The final form products do not contain THC isolate as an ingredient. HSC 111920(g)(1)(B)(iii). _____ **(initials)**
   c) The products do not contain HHC. _____ **(initials)**
   d) 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). _____ **(initials)**
   e) The products are not medical devices. HSC 111921.5(a)(1). _____**(initials)**
   f) The products are not prescription drugs or non-prescription drugs. HSC 111921.5(a)(2). _____ **(initials)**
   g) The products do not contain nicotine or tobacco. HSC 111921.5(a)(3). _____**(initials)**
   h) The products are not alcoholic beverages. HSC 111921.5(a)(4). _____**(initials)**
   i) Manufacturing is in a commercial location. 17 CCR 23210(b). _____**(initials)**
   j) 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)**
   k) The products are labeled with serving size per package. HSC 111922 _____**(initials)**

2. **Certificate of Analysis (COA)**
   a) Each required COA will be truthful and accurate. _____ **(initials)**
   b) Each required COA will be from an independent testing laboratory confirms the mass of the industrial hemp extract used in the final form product does not exceed 0.3% total THC, including but not limited to Delta-8 THC, Delta-9 THC, and Delta-10 THC, HSC 111921(a)(1). _____**(initials)**

3. **Independent Testing Laboratory**
   a) The testing laboratory does not have a direct interest in the entity for which testing is being done. HSC 111920(e)(1). _____ **(initials)**
   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). _____ **(initials)**
   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). _____ **(initials)**
   d) The testing laboratory is compliant with HSC 111920(e)(4)(A) or HSC 111920(e)(4)(B). _____ **(initials)**
      (1) Licensed by the California Department of Cannabis Control?
      Yes ○ No ○
      (2) ISO 17025 accredited? Yes ◉ No ○

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). _____ **(initials)**
   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 are no health-related statement that is untrue on the label of the products or published or disseminated in advertising or marketing. HSC 110407. _____ **(initials)**
   b) Advertising and marketing does not directly target children or persons who are pregnant or breastfeeding. HSC 111926(b). _____ **(initials)**
   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). _____ **(initials)**
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). _____ **(initials)**
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). _____**(initials)**

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). _____**(initials)**
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 111925.2(c). _____ **(initials)**
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). _____ **(initials)**
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). _____ **(initials)**
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). _____**(initials)**
4. All COAs will be 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). _____**(initials)**
5. Food and beverage products are prepackaged. HSC 111922(b). _____**(initials)**
6. Food and beverage products are shelf stable. HSC 111922(b). _____**(initials)**
7. 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). _____ **(initials)**
8. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the product name. HSC 111926.2(a)(1)(A). _____**(initials)**
9. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the name of the product's manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.2(a)(1)(B). _____**(initials)**
10. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the batch number, which matches the batch number on the product. HSC 111926.2(a)(1)(C). _____**(initials)**
11. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the concentration of cannabinoids

present 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). _____**(initials)**

12. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the levels within the product batch of contaminants. HSC 111926.2(a)(1)(E). _____ **(initials)**
13. Packaging and labeling on the products include the product expiration or best by date, as needed. HSC 111926.2(a)(2). _____**(initials)**
14. 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). _____**(initials)**
15. 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). _____**(initials)**
16. 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. Pet food products are prepackaged. HSC 111922(b). _____ **(initials)**
2. Pet Food products are shelf stable. HSC 111922(b). _____**(initials)**
3. Products are manufactured pursuant to good manufacturing practices. HSC 111922.3(b). _____**(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). _____**(initials)**
2. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the product name. HSC 111926.3(a)(1)(A). _____**(initials)**
3. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the name of the product’s manufacturer, packer, or distributor, and their address and telephone number. HSC 111926.3(a)(1)(B). _____**(initials)**
4. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the batch number, which matches the batch number on the product. HSC 111926.3(a)(1)(C). _____**(initials)**
5. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the concentration of cannabinoids present 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). _____**(initials)**

6. The label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis includes the levels within the product batch of contaminants. HSC 111926.3(a)(1)(E). _____ **(initials)**
7. Packaging and labeling on the products include the product expiration or best by date, as needed. HSC 111926.3(a)(2). _____ **(initials)**
8. 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). _____ **(initials)**
2. Inhalable products are not sold to consumers under 21 years of age. HSC 111929. _____ **(initials)**
3. Additional questions for industrial hemp inhalable products:
   a) Do products contain flavorings other than natural terpenes? HSC 111929.2(a).
      Yes ◉ No ○
   b) Do products contain polyethylene glycol (PEG)? HSC 111929.2(b).
      Yes ○ No ◉
   c) Do products contain vitamin E acetate? HSC 111929.2(c).
      Yes ○ No ○
   d) Do products contain medium chain triglycerides (MCT oil)? HSC 111929.2(d).
      Yes ◉ No ○
   e) Do products contain squal**e**ne or squal**a**ne? HSC 111929.2(e).
      Yes ○ No ◉

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 maybe grounds for denial, revocation or suspension 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 product(s) of manufacture of this application. I also consent to inspection(s) including but not limited to manufacturing, holding, and distributing site(s), records, etc. by authorized agent(s) of CDPH. I acknowledge that refusal to submit to inspection and commission of violations under Sherman Law may be grounds for denial, suspension and/or revocation of CDPH registration/licensure and may be subject to other penalties.

Owner's Signature: _____ Owner's Printed Name: _____

Title: _____ Date: _____