

## **Summary of Express Terms**

These amendments add a new Part 1005 to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, regulating the processing and retail sale of cannabinoid hemp in New York State.

Section 1005.1 defines terms used in Part 1005, including but not limited to “cannabinoid hemp product,” “cannabinoid hemp processor,” “cannabinoid hemp retailer,” “hemp extract,” and “used for human consumption.”

Section 1005.2 establishes licensure and application requirements for cannabinoid hemp processors in New York State. Any person extracting or manufacturing cannabinoid hemp in New York State is required to obtain a license from the New York State Department of Health (Department). Among other requirements, cannabinoid hemp processor applications must be accompanied by a summary and description of the products the applicant intends to make, proof of product liability insurance, evidence of good manufacturing practices, and copies of the organizational documents of the applicant. Cannabinoid hemp processor applications must be submitted with a \$1,000 application fee or a \$500 application fee for applicants seeking only to manufacture, and not extract, cannabinoid hemp.

Section 1005.3 sets out the requirements to apply as a cannabinoid hemp retailer in New York State. Any person selling cannabinoid hemp to consumers must obtain a license from the Department. Among other requirements, cannabinoid hemp retail applications must be accompanied by a summary and description of the type of cannabinoid hemp products the

retailer intends to sell, the name and country of origin of any manufacturer or distributor the retailer intends to source from, an attestation that the applicant will not sell inhalable cannabinoid hemp products to consumers under 21 years old, and if applicable, proof of a certificate of authority from the Department of Taxation and Finance. All applications must be submitted with a \$300 license fee for each retail location to be licensed by the Department.

Section 1005.4 describes the criteria the Department will use to determine if an applicant's license should be approved or denied. If an applicant is approved as a cannabinoid hemp processor, the approved applicant must submit the following before receiving the final license: a copy of the certificate of occupancy for the facility, a copy of the applicant's evidence of a Good Manufacturing Practices (GMP) audit, proof of product liability insurance and the license fee of \$3,500 for extracting or \$1,000 for manufacturing only. The license fees for cannabinoid hemp retailers is \$300 per location selling cannabinoid hemp products. Processor licenses are valid for two years and retailer licenses are valid for one year.

Section 1005.5 outlines the requirements for license renewal.

Section 1005.6 sets out the rules around transfers and amendments to licenses, including changes in ownership. All licenses under this Part are non-transferable, except with the prior written approval of the Department.

Section 1005.7 outlines the requirements for cannabinoid hemp processors. Cannabinoid hemp processors are required to maintain qualified third-party GMP certification for the duration of the license term. Processors must retain records of the extraction and manufacturing process

including but not limited to the source of hemp or hemp extract, the calibration and inspection of all equipment or instruments, the disposal of hemp extract or hemp by-product, the tracking and documentation of  $\Delta 9$ -Tetrahydrocannabinol (THC), and all testing records of samples from lots or batches of product. This section also imposes security and sanitary standards on the licensee to keep unauthorized individuals from entering the licensed premise and to ensure the facility is safe and sanitary to create products for human consumption. Intermediate sales of hemp extract containing up to 3.0% THC are authorized, provided that the sale is between licensed processors in New York State and the proper documents accompany the extract during transport. All solvents and methods used to process hemp extract must be approved by the Department.

Section 1005.8 outlines the cannabinoid hemp product requirements to be sold at retail. Product requirements include but are not limited to: not containing more than 0.3% total  $\Delta 9$ -Tetrahydrocannabinol concentration; not containing tobacco or alcohol; not being in the form of an injectable, inhaler, or flower product labeled or advertised for the purpose of smoking, or in the form of a cigarette, cigar or pre-roll, or packaged or combined with other items designed to facilitate smoking; if sold as a food or beverage product, not have more than 25 mg of cannabinoids per product; and, if sold as an inhalable cannabinoid hemp product, a number of additional safety measures.

Section 1005.9 is added to outline the requirements of cannabinoid hemp packaging and labeling. All cannabinoid hemp products need to be labeled with the total milligram content of cannabidiol (CBD), THC, and marketed cannabinoids in the product, and include the milligrams per serving for each. All products are required to have a scannable barcode or QR code which links to a certificate of analysis and the packaging is prohibited from being attractive to

consumers under 18 years old. Products are also required to list appropriate warnings for consumer awareness.

Section 1005.10 establishes laboratory testing requirements for cannabinoid hemp products. Cannabinoid hemp processors must have cannabinoid hemp products tested at a laboratory approved to test medical marijuana or that meets minimum requirements established in this section, including maintaining ISO/IEC 17025 accreditation and validating the methods used for testing. This section describes which analytes are part of required testing and further establishes limits for cannabinoids, heavy metals, microbial impurities, mycotoxins, residual pesticides, residual solvents and processing chemicals. Cannabinoid hemp products that contain levels of analytes that deviate from the allowable limits are considered adulterated and must be destroyed.

Section 1005.11 outlines requirements for cannabinoid hemp retailers. Cannabinoid hemp retailers can only sell products that are manufactured, packaged, labeled and tested according to the standards outlined in regulations and can only sell inhalable cannabinoid hemp products to consumers over 21 years old. All licensees must post their license in a conspicuous manner and maintain sufficient inventory and sales records. The Department also has the authority to inspect cannabinoid hemp retailers and take samples of cannabinoid hemp products to ensure compliance with this Part.

Section 1005.12 establishes advertising requirements for cannabinoid hemp processors and retailers, including the prohibition on false or misleading statements and medical claims.

Section 1005.13 establishes standards and requirements to certify a product as a New York Hemp Product.

Section 1005.14 outlines general prohibitions, including the requirement that all entities manufacturing or selling cannabinoid hemp products in New York State must hold a valid license under this Part. All cannabinoid hemp products must comply with manufacturing, laboratory testing, and packaging and labeling requirements outlined in the proposed regulations. All cannabinoid hemp products offered for retail sale in New York State must have a concentration of no more than 0.3% total  $\Delta 9$ -Tetrahydrocannabinol. Requirements are also established for the transportation of hemp extract, including the requirement that it be transported in a fully enclosed vehicle or container and accompanied by proof of origin and a certificate of analysis. Finally, this section requires that anyone distributing cannabinoid hemp products manufactured out of state, to cannabinoid hemp retailers within the state, be permitted by the Department.

Section 1005.15 describes specific prohibitions that pertain to cannabinoid hemp processors including the transfer of a license without approval from the Department and the manufacture of a potentially hazardous food containing cannabinoid hemp. Further, no cannabinoid hemp processor may conduct final product testing for the licensee's own products to satisfy the testing requirements established in the proposed regulations. Cannabinoid hemp processors may not sell cannabinoid hemp products directly to consumers for final sale without obtaining a cannabinoid hemp retail license and cannabinoid hemp processors may not sell cannabinoid hemp extract to anyone in New York unless the purchaser is a cannabinoid hemp processor or a registered organization in the Department's Medical Marijuana Program.

Section 1005.16 describes specific prohibitions for cannabinoid hemp retailers, including age restrictions for the sale of inhalable cannabinoid hemp products and a prohibition on the sale of cannabinoid hemp products that do not meet product requirements or consumer safety standards outlined in this Part.

Section 1005.17 establishes penalties for non-compliance with the requirements of Article 33-B of the Public Health Law and this Part. Penalties include fines that increase with the number of violations, such that the first violation incurs a fine of up to \$1,000, the second violation within a three year period incurs a fine of up to \$5,000, and the third violation or any additional violation incurs a fine of up to \$10,000. This section further allows the Department to limit, suspend, revoke or annul a license. If a licensee violates the proposed regulations three times in a five-year period, the licensee may be deemed ineligible to manufacture or sell cannabinoid hemp products for a period of five years.

Section 1005.18 provides the Department authority to issue permits for distribution of out of state cannabinoid hemp products, temporary retail sale and to persons holding a CBD processor research partnership agreement with the New York State Department of Agriculture and Markets. Permits are valid for one year unless otherwise established by the Department.

Section 1005.19 adds a severability clause for the Part.

Section 1005.20 incorporates by reference certain federal regulations.

Section 1005.21 establishes the effective dates for this Part.

Pursuant to the authority vested in the Commissioner of Health by Section 3398-a of the Public Health Law (PHL), Chapter XIII of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, and a new Part 1005 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

The title of Chapter XIII is amended to read as follows:

Chapter XIII

MEDICAL [USE OF] MARIHUANA AND CANNABINOID HEMP

A new Part 1005 is added to read as follows:

Part 1005

CANNABINOID HEMP

Section 1005.1 Definitions

For purposes of this Part, the following terms shall have the following meanings:

(a) *Broad spectrum* means hemp extract or cannabinoid hemp product containing multiple cannabinoids, but where  $\Delta$ 9-Tetrahydrocannabinol (THC) has been removed to non-detectable levels using a fit-for-purpose method, with a limit of quantification of less than 0.01% THC.



(b) *Cannabidiol* or *CBD* means the naturally occurring hemp-derived phytocannabinoid cannabidiol, but does not include synthetic cannabidiol.

(c) *Cannabinoids* means any hemp-derived phytocannabinoid, including but not limited to, Tetrahydrocannabinol (THC), tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC), cannabicyclol (CBL), cannabivarin (CBV), tetrahydrocannabivarin (THCV), cannabidivarin (CBDV), cannabichromevarin (CBCV), cannabigerovarin (CBGV), cannabigerol monomethyl ether (CBGM), cannabielsoin (CBE), cannabicitran (CBT). Cannabinoids do not include synthetic cannabinoids, as that term is defined in subdivision (g) of section 3306 of the Public Health Law and section 9-1.1 of this Title.

(d) *Cannabinoid hemp product* means hemp or any product manufactured or derived from hemp, including hemp derived terpenes, in its final form, used for human consumption. Cannabinoid hemp product shall not include cosmetics.

(e) *Cannabinoid hemp retailer* means a person licensed by the department to sell cannabinoid hemp products, including via the internet, to consumers in New York State.

(f) *Cannabinoid hemp processor* means a person licensed by the department to extract hemp extract and/or manufacture cannabinoid hemp products in New York State, whether in intermediate or final form, to be used for human consumption.

(g) *Certificate of analysis* means a certified report from an independent third-party laboratory meeting all of the requirements of section 1005.10 of this Part, describing its analytical testing and results.

(h) *Corrective action plan* means a plan submitted by a licensee and approved by the department under this Part for the licensee to correct a violation or non-compliance with this Part.

(i) *Cosmetic* means a cosmetic meeting the requirements of section 321 of Title 21 of the United States Code and recognized as such by the department.

(j) *Distillate* means hemp extract where a segment of one or more cannabinoids from an initial extraction are selectively concentrated through heating and cooling, with all impurities removed.

(k) *Distribute* means to offer or sell cannabinoid hemp products to a cannabinoid hemp retailer, for retail sale to consumers within New York state.

(l) *Extract* or *Extraction* means the process of concentrating or isolating one or more cannabinoids from hemp or cannabinoid hemp.

(m) *Flower product* means any form of cannabinoid hemp product consisting of the flower, buds, leaves, or stems of the hemp plant, including trimmings thereof, intended for retail sale to consumers with minimal processing. Provided, however that flower product shall not include:

(1) any food, food ingredient, food additive, or items that are generally recognized as safe, pursuant to state or federal law; or

(2) any other product, including microgreens, sprouts or certain hemp leaf products, as determined by the Department.

(n) *Full spectrum* means hemp extract or cannabinoid hemp product containing multiple hemp-derived cannabinoids, terpenes, and other naturally occurring compounds, processed without intentional complete removal of any compound and without the addition of isolated cannabinoids, with a final  $\Delta 9$ -Tetrahydrocannabinol concentration of not greater than 0.3%.

(o) *Hemp* means the plant *Cannabis sativa* L. and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a  $\Delta 9$ -Tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.

(p) *Hemp extract* means all derivatives, extracts, cannabinoids, isomers, acids, salts of isomers derived from hemp and used for human consumption, with a  $\Delta 9$ -Tetrahydrocannabinol concentration of not more than an amount determined by the department pursuant to this Part. Hemp extract shall not include:

(1) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or

(2) any extract derived from hemp that is not used for human consumption.

(q) *Isolate* means hemp extract or cannabinoid hemp product comprised of 95 percent or more of a single cannabinoid compound.

(r) *Lot or batch* means any cannabinoid hemp product produced during a period of time under similar conditions and identified by a specific code that allows traceability.

(s) *Manufacture* means to prepare, treat, modify, compound, process, package or otherwise manipulate hemp or hemp extract into a cannabinoid hemp product. Manufacturing shall not include:

(1) growing, cultivating, cloning, harvesting, drying, curing, grinding or trimming when authorized pursuant to Article 29-A of the Agriculture and Markets Law; or

(2) extraction as defined in subdivision (1) of this Section.

(t) *New York Hemp Product* means a cannabinoid hemp product that is derived from hemp exclusively grown, extracted and manufactured in New York, in compliance with section 1005.13 of this Part.

(u) *Person* means an individual, partnership, corporation, limited liability company, association, or any business entity or institution of higher education, by whatever name designated and whether or not incorporated.

(v) *Serious adverse event* means a medical occurrence associated with the use of a cannabinoid hemp product in a human that results in one or more of the following outcomes: death, a life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

(w) *Total Δ9-Tetrahydrocannabinol concentration* means  $[\Delta 9\text{-Tetrahydrocannabinol}] + (0.877 \times [\text{tetrahydrocannabinolic acid}])$ .

(x) *Used for human consumption* means intended by the manufacturer or distributor to be:

- (1) used for human consumption for its cannabinoid content; or
- (2) used in, on or by the human body for its cannabinoid content.

Section 1005.2 Application for cannabinoid hemp processor license.

(a) No person or entity shall extract hemp extract or manufacture cannabinoid hemp product, or hold itself out as a cannabinoid hemp processor, unless it is in compliance with Article 33-B of the Public Health Law and this Part and is licensed by the department as a cannabinoid hemp processor.

(b) An application for licensure shall be submitted to the department on a form prescribed by the department which shall include the following:

- (1) the name, address, telephone number and email address of the applicant;
- (2) identification of all real property, buildings and facilities that will be used in the extracting of hemp extract or manufacturing of cannabinoid hemp;
- (3) the days and hours of operation;

(4) the Federal employer identification number of the applicant;

(5) for applicants extracting hemp extract, identification of all extraction methods that will be used to carry out the extracting;

(6) proof of New York State Workers' Compensation and Disability Insurance coverage, or a Certificate of Attestation of Exemption from coverage;

(7) a summary and description of the applicant's:

(i) source(s) of hemp and hemp extract to be used by the licensee; and

(ii) cannabinoid hemp products to be manufactured;

(8) a statement that the applicant's standard operating procedures will incorporate any language or requirements provided by the department and adequately address quality assurance, security, and a plan to ensure all hemp and hemp extract obtained by the applicant meets the requirements of this Part.

(9) evidence that Good Manufacturing Practices (GMP) will be used in the extraction of hemp extract and manufacturing of cannabinoid hemp products. Such evidence shall include one of the following:

(i) proof of a qualified third-party GMP audit of the applicant's extraction and manufacturing processes; or

(ii) a detailed plan for obtaining a qualified third-party GMP audit within six months of approval of the application and before beginning operations as a cannabinoid hemp processor in New York State;

(10) a copy and description of any other license(s) issued by state or federal authorities related to the operations of the licensee or the facility where licensed activity will occur;

(11) a description of any other businesses or business activities conducted on the premises to be licensed;

(12) copies of the organizational documents of the applicant;

(13) a statement attesting that the applicant and those in control of the entity, meaning a person that has the ability to direct the activity of the applicant or licensee, including principals, officers or others with such control, are of good moral character;

(14) a statement attesting that the applicant will comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the license;

(15) a statement attesting that the applicant has the experience and competency to undertake the activities for which licensure is sought; and

(16) any other information as may be required by the department.

(c) Applications under this section shall be accompanied by a non-refundable application fee of \$1,000 for extraction and manufacturing, and \$500 for manufacturing only.

(d) Applicants shall verify the truth and accuracy of the information contained in the application. The department, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or omits a material fact.

#### Section 1005.3 Application for Cannabinoid Hemp Retail License.

(a) No person shall offer or sell cannabinoid hemp products to consumers in New York State, or hold itself out as a cannabinoid hemp retailer, unless it is in compliance with Article 33-B of the Public Health Law and this Part and is licensed by the department as a cannabinoid hemp retailer.

(b) An application for licensure shall be submitted to the department on a form prescribed by the department, which shall include the following:

(1) the name, address, telephone number and email address of the applicant;



(2) the physical address of any real property where the applicant intends to operate, the days and hours of operation of such retail facility, and for any online retailer, the internet address of the applicant;

(3) the name, and license number to the extent practicable, of the manufacturer, packer, distributor, or cannabinoid hemp processor, and state or country where the manufacturer, packer, or distributor is located, for all cannabinoid hemp products the applicant intends to offer for sale;

(4) a summary and description of the types and forms of cannabinoid hemp products the applicant intends to offer for sale;

(5) a statement attesting that the applicant will not sell inhalable cannabinoid hemp products or flower products to consumers under 21 years of age;

(6) a statement attesting that the applicant and those in control of the entity, meaning a person or persons that have the ability to direct the activity of the applicant or licensee, including principals, officers or others with such control, are of good moral character;

(7) a statement attesting that the applicant will comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the license;

(8) a statement attesting that the applicant will not distribute or sell any cannabinoid hemp product in the form of an injectable, inhaler, or flower product clearly labeled or advertised for

the purpose of smoking or in the form of a cigarette, cigar or pre-roll or otherwise packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes, or any other disallowed form as determined by the department;

(9) proof of a certificate of authority from the New York State Department of Taxation and Finance, as applicable; and

(10) any other information as may be required by the department.

(c) All applications under this section shall be accompanied by a refundable license fee of \$300 for each retail facility to be licensed by the department.

(d) Applicants shall attest to the truth and accuracy of the information contained in the application. The department, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or omits a material fact.

#### Section 1005.4 License issuance and denial.

(a) An application for licensure under this Part shall only be approved by the department if:

(1) a complete application has been submitted to the department, along with all necessary fees;

(2) the application demonstrates, to the satisfaction of the department, that the applicant will operate in accordance with Article 33-b of the Public Health Law and this Part;

(3) the applicant is ready, willing and able to properly carry on the activities set forth in the application; and

(4) the applicant is of good moral character.

(b) In determining whether to deny a license application, including an application for renewal, the department may consider the following factors with respect to the applicant, its owner(s) and any affiliated person, including parties with a controlling interest:

(1) false representation or omission of a material fact in filing the license application;

(2) failure to supply further information necessary to process the license application, within thirty days of the department's written request, without satisfactory explanation;

(3) conviction of any crime or sustained charges of administrative violations of state or federal laws, rules or regulations, related to the operation of a site growing, extracting, manufacturing or selling cannabis, hemp or cannabinoid hemp, in accordance with Article 23-A of the Correction Law. Convictions qualifying for expungement pursuant to section 160.50 of the Criminal Procedure Law shall not be considered for purposes of this subdivision;

(4) a pattern of deficiencies, including but not limited to:

- (i) refusal or inability to produce records or reports as requested by the department;
  - (ii) failure to correct deficiencies in accordance with an approved corrective action plan;
  - (iii) deviation from regulations or standard operating procedures so as to jeopardize the quality of hemp extract or cannabinoid hemp products; and
  - (iv) refusal to provide department employees with access to the premises;
- (5) knowledge of sale of cannabinoid hemp products not meeting the requirements of this Part;  
and
- (6) general failure to comply with the requirements of this Part.
- (c) Denial of a license shall preclude the applicant from being licensed as a cannabinoid hemp processor or cannabinoid hemp retailer, either directly or indirectly through any other person.
- (d) No license application shall be considered for any applicant who is substantially the same as an applicant who has been denied a license within six months of a determination by the department denying such application. In the event an applicant receives two successive license denials, no license application shall be considered for that applicant within two years of the last determination by the department denying a previous application.

(e) The department will prioritize applications from applicants who previously held a valid research partnership agreement with the New York State Department of Agriculture and Markets pursuant to Article 29-A of the New York State Agriculture and Markets Law. All other applications will be reviewed in the order they are received by the department.

(f) For applicants seeking licensure as a cannabinoid hemp processor, the department may provisionally approve the application. Before a cannabinoid hemp processor license is issued, and the applicant can begin extracting or manufacturing, the provisionally approved applicant must first satisfy the following requirements:

(1) a copy of a certificate of occupancy, or its equivalent, demonstrating compliance with all local building codes;

(2) a copy of the approved applicant's qualified third-party GMP certification;

(3) payment of licensure fee as follows:

(i) Cannabinoid Hemp Processor – Extraction and Manufacturing: \$3,500 per location; or

(ii) Cannabinoid Hemp Processor – Manufacturing Only: \$1,000 per location;

(4) proof of sufficient product liability insurance for all manufactured cannabinoid hemp products; and

(5) evidence, to the department's satisfaction, that the applicant will be able to comply with this Part, which may include an onsite inspection.

(g) If a provisionally approved applicant fails to satisfy the requirements in subdivision (f) of this section within six months, the provisional approval will be revoked and the application denied; provided the applicant may request additional time and shall have the opportunity to demonstrate to the department a reasonable documented effort to complete the requirements of subdivision (f) of this section.

(h) Cannabinoid hemp processor licenses shall be valid for two years from the date of issuance of the license.

(i) A cannabinoid hemp processor seeking to terminate its license shall submit a withdrawal notice to the department at least 30 days prior to termination, along with a plan for shutting down operations at the licensed facility. Any licensing fees paid or invoiced prior to notice of withdrawal are not eligible for refund.

(j) Cannabinoid hemp retailer licenses shall be valid for one year from the date of issuance of the license.

(k) Cannabinoid hemp retailer applicants who submit a completed application to the department on or before June 1, 2021 may sell cannabinoid hemp products at retail to consumers before having their license approved or denied by the department, provided that the cannabinoid hemp retail applicant adheres to all requirements of this Part.

#### Section 1005.5 License Renewal

(a) An application to renew any license issued under this Part shall be filed with the department not more than 90 days nor less than 30 days prior to the expiration thereof. If a renewal application is not filed at least 30 days prior to the expiration thereof, the department may determine that the license shall expire and become void on such expiration date.

(b) Renewal applications shall be accompanied by a non-refundable application fee and a refundable license fee, as follows:

(1) Cannabinoid Hemp Processor – Extraction and Manufacturing: \$1,000 application fee, \$3,500 license fee;

(2) Cannabinoid Hemp Processor – Manufacturing Only: \$500 application fee, \$1,000 license fee; or

(3) Cannabinoid Hemp Retailer: \$300 license fee per retail location.

(4) the license fee shall be returned if the licensee's renewal application is not granted.

(c) The application for renewal shall be submitted to the department, in a manner prescribed by the department, and include such information as the department may require.

(d) The department shall determine whether to renew an applicant's license based on the relevant factors in section 1005.4 of this Part.

#### Section 1005.6 Transferability, License Amendment and Change in Ownership or Control

(a) Licenses issued under this Part shall be effective only for the licensee and shall specify the following information:

(1) name of the licensee;

(2) address of the real property, or if applicable the online retailer website, where the licensed activities may take place;

(3) date of issuance;

(4) date of expiration;

(5) license number; and



(6) list of activities the licensee is permitted to perform under the license.

(b) Licenses shall not be transferable or assignable without prior written approval of the department including, without limitation, to another licensee. A change in majority ownership or controlling interest in the license or person holding the license, shall constitute a transfer of the license.

(c) To obtain approval from the department for the transfer of a license, a transferee must submit an application to the department, in a manner prescribed by the department, demonstrating an ability to operate the license in compliance with this Part, along with an application fee pursuant to section 1005.2 or 1005.3, as applicable.

(d) The department may deny an application for transfer of a license if the application fails to demonstrate that the transferee will comply with all of the requirements of this Part, or if the licensee has a record of poor performance, meaning two or more violations pursuant to section 1005.17 of this Part, within the past two-years.

(e) A licensee may amend a license to add or delete permitted activities or change the location of a licensed facility by submitting a written request to the department along with an application fee pursuant to section 1005.2 or 1005.3, as applicable.

(f) A request to add permitted activities shall be reviewed by the department in accordance with section 1005.4 of this Part.

## Section 1005.7 Requirements for Cannabinoid Hemp Processors

(a) All cannabinoid hemp processors shall:

(1) extract hemp extract and/or manufacture cannabinoid hemp products to GMP standards and maintain a qualified third-party certification, to the satisfaction of the department, for the applicable GMP standard(s) for the duration of the license;

(2) maintain standard operating procedures and quality control standards to ensure consistency of hemp extract and/or cannabinoid hemp products, including but not limited to product purity, strength and composition;

(3) maintain sufficient records to demonstrate that any hemp or hemp extract used by the licensee was grown, derived, extracted and transported in accordance with applicable laws and licensing requirements of the jurisdiction(s) from which such hemp or hemp extract was sourced. Such records shall include any pesticides used in the growing of such hemp, date(s) each shipment was received, adequate chain of custody to demonstrate from whom the licensee purchased such hemp or hemp extract, and certificates of analysis. For hemp received from an out-of-state grower, processors shall also maintain records of the out-of-state grower registration or license number in the respective jurisdiction;

(4) keep all designated extracting and manufacturing areas safe and sanitary, including but not limited to ensuring that such areas are adequately lit, cleaned, smoke-free, and no food is consumed in such areas;

(5) provide all employees performing extraction or manufacturing with adequate training and proper safety equipment;

(6) manufacture cannabinoid hemp products in accordance with section 1005.8 of this Part;

(7) test a statistically significant number of cannabinoid hemp products per lot or batch at a third-party testing laboratory meeting all the requirements in section 1005.10 of this Part, and maintain a certificate of analysis for all samples tested;

(8) maintain sufficient records pertaining to the calibration and inspection of instruments used in extraction and manufacturing of cannabinoid hemp products;

(9) report, in a frequency and manner prescribed by the department, the total production and sales of the licensee during such reporting period;

(10) ensure the security of the licensed premises to prevent unauthorized individuals from entering the facility and to prevent hemp extract and/or cannabinoid hemp products from being diverted from the facility;

(11) not use synthetic cannabinoids, or  $\Delta 8$ -tetrahydrocannabinol or  $\Delta 10$ -tetrahydrocannabinol created through isomerization, in the extraction or manufacturing of any cannabinoid hemp products;

(12) assign a lot or batch number to each lot of hemp extract or cannabinoid hemp product, extracted or manufactured by a licensee; and

(13) maintain any and all records required by this Part for at least three years and immediately produce such records upon request of the department.

(b) Possession and the intermediate sale of hemp extract by and between licensed cannabinoid hemp processors, is permitted, provided when such extract leaves the licensed premises it is accompanied by a certificate of analysis certifying that the extract is less than three (3) percent THC and a copy of the cannabinoid hemp processor's license, and further provided such hemp extract is only transported intra-state.

(c) Licensees shall monitor complaints from cannabinoid hemp retailers and consumers and have a mechanism in place to notify the licensee's supply chain to recall products when directed by the department or as deemed appropriate by the licensee. Licensees shall notify the department within 24 hours of learning of a serious adverse event.

(d) Licensees shall ensure the proper disposal, beyond reclamation, of any hemp extract or by-product from the extraction and manufacture process with a total  $\Delta 9$ -Tetrahydrocannabinol concentration greater than three-tenths of a percent (0.3%) and which will not be used or subject to further processing. Such disposal shall render the hemp extract or by-product unusable for any intoxicating purpose. Licensees shall maintain records to document and track any  $\Delta 9$ -Tetrahydrocannabinol extracted from hemp or found within hemp extract throughout the

extraction and manufacturing process, including records pertaining to the amount used in cannabinoid hemp products and the disposal of all hemp extract,  $\Delta 9$ -Tetrahydrocannabinol or by-product;

(1) licensees shall dispose of any cannabinoid hemp product that is outdated, damaged, deteriorated, contaminated or otherwise deemed not appropriate for sale; and

(2) licensees shall dispose of liquid, chemical and hazardous waste in accordance with applicable federal, state and local laws and regulations.

(e) The department may conduct random sampling and testing of hemp, hemp extract, cannabinoid hemp products, or any solvents, chemicals, or materials used by the licensee, unannounced, at any time during normal business hours of the licensee.

(f) If a cannabinoid hemp processor is authorized to perform extraction, the processor shall:

(1) only extract using methods approved by the department, on the licensed premises, and using employees and equipment sufficient to ensure safe extraction; and

(2) use only those solvents that are approved by the department. Solvent-based extraction must be completed in a commercial, professional grade, closed-loop system capable of recovering the solvent used for extraction.

## Section 1005.8 Cannabinoid hemp product requirements

(a) All cannabinoid hemp products distributed or offered for retail sale in New York State shall:

(1) be manufactured in accordance with Parts 101, 111 or 117 of Title 21 of the Code of Federal Regulations, as appropriate for the type of product being manufactured and as otherwise determined appropriate by the department in guidance or future regulation.

(2) contain no more than three-tenths of a percent (0.3%) total  $\Delta$ 9-Tetrahydrocannabinol concentration. The department may through future regulation impose a total THC cap for the purpose of protecting public health, which shall include detectable levels of total  $\Delta$ 9-Tetrahydrocannabinol,  $\Delta$ 8-Tetrahydrocannabinol and  $\Delta$ 10-Tetrahydrocannabinol in milligrams per serving and milligrams per package for cannabinoid hemp products based on the product form, volume, number of servings, and ratio of CBD to THC;

(3) not contain liquor, wine, beer, cider or meet the definition of an alcoholic beverage as defined in section 3 of the Alcohol Beverage Control Law;

(4) not contain tobacco or nicotine in the product;

(5) not be in the form of an injectable, inhaler, product including cigarette, cigar or pre-roll, or any other disallowed form as determined by the department;

- (6) accurately reflect testing results and not contain less than 80 percent or more than 120 percent of the concentration of total cannabinoid content as listed on the product label;
  - (7) comply with packaging and labeling standards in section 1005.9 of this Part;
  - (8) be prepackaged and not added to food or any other consumable products at the point of sale;
  - (9) be shelf stable;
  - (10) comply with product testing standards in section 1005.10 of this Part; and
  - (11) not contain synthetic cannabinoids, or cannabinoids created through isomerization, including  $\Delta 8$ -tetrahydrocannabinol and  $\Delta 10$ -tetrahydrocannabinol.
- (b) If the cannabinoid hemp product is a food or beverage manufactured under Part 117 of Title 21 Code of Federal Regulations, it shall not contain more than 25 milligrams of total cannabinoids per individually packaged product. If the cannabinoid hemp product is a supplement manufactured under Part 111 of Title 21 Code of Federal Regulations, it shall not contain more than 3,000 milligram of total cannabinoids per product, with no more than 75 milligrams per individual serving.
- (c) If the cannabinoid hemp product contains multiple servings which are not individually wrapped, premeasured, separated or delineated, it shall include a measuring device such as a

measuring cap, cup or dropper with the product packaging. Hash marks on the package shall not qualify as a measuring device.

(d) All inhalable cannabinoid hemp products shall meet the following additional requirements:

(1) be a closed system with a pre-filled disposable cartridge that attaches to a rechargeable battery, or a single-use product that cannot be recharged;

(2) electronic vaporization devices shall have internal or external temperature controls to prevent combustion and have a heating element made of inert material such as glass, ceramic or stainless steel and not plastic or rubber;

(3) except for hemp-derived terpenes, excipients and ingredients must be pharmaceutical grade unless otherwise approved by the department, and shall not include:

(i) synthetic terpenes;

(ii) polyethylene glycol (PEG);

(iii) vitamin E acetate;

(iv) medium chain triglycerides (MCT oil);



(v) medicinal compounds;

(vi) illegal or controlled substances;

(vii) artificial food coloring;

(viii) benzoic acid;

(ix) diketones; and

(x) any other compound or ingredient as determined by the department in regulation;

(4) not contain any flavors or flavoring agents, except for hemp-derived terpenes; and

(5) include a department approved symbol, as set out in future regulation, in a manner that is clear and conspicuous.

#### Section 1005.9 Packaging and labeling of cannabinoid hemp products.

(a) All cannabinoid hemp products distributed or offered for retail sale in New York State shall include the following information on the product label or packaging:

(1) if the cannabinoid hemp product is consumed through ingestion, including sublingual or oral absorption, comply with the requirements in Title 21 Code of Federal Regulations Part 101 and include a nutritional or supplement fact panel that is based on the number of servings within the container;

(2) a list of all ingredients in descending order of predominance by weight in the product;

(3) the number of servings per outer package or container, including the milligrams per serving and the milligrams per package of:

(i) CBD;

(ii) “Total THC” or “THC” which for the purposes of product labeling shall include detectable levels of total  $\Delta$ 9-Tetrahydrocannabinol,  $\Delta$ 8-Tetrahydrocannabinol and  $\Delta$ 10-Tetrahydrocannabinol; and

(iii) any other marketed cannabinoid;

(4) an expiration or best by date if applicable;

(5) a lot or batch number;

(6) the name of the cannabinoid hemp processor or out of state manufacturer, packer or distributor;

(7) a scannable bar code or QR code linked to a downloadable certificate of analysis, or linked to a website where the certificate of analysis can be downloaded;

(8) the country or (countries) of origin from which hemp used in the product was sourced;

(9) a means for reporting serious adverse events or side effects; and

(10) any other marking, statement or symbol as required by the department in regulation.

(b) No cannabinoid hemp product packaging shall imitate a candy label or use cartoons or other images popularly used to advertise to children or otherwise be marketed to anyone under 18 years of age, or for inhalable cannabinoid hemp products and flower product, to anyone under 21 years of age.

(c) All cannabinoid hemp products shall be packaged in tamper-evident packaging that minimizes oxygen and light exposure to prevent degradation of the product and cannabinoids.

(d) All cannabinoid hemp products shall be accompanied by recommended serving and clear usage instructions.

(e) All cannabinoid hemp products claiming to be “isolate,” “full spectrum,” “broad spectrum,” or “distillate” shall comply with the applicable definition contained in this Part.

(f) All cannabinoid hemp products offered for retail sale shall include the following warnings on the product label or packaging, in a manner that is clear and conspicuous:

(1) keep out of the reach of children;

(2) that the product is derived from hemp and may contain THC which could result in a failed drug test. Provided however, this warning may be omitted for cannabinoid hemp products that are: topically applied; made exclusively using an “isolate;” or made from “broad spectrum” hemp extract derived entirely from hemp grown, extracted, and manufactured in New York State;

(3) that the product has not been evaluated by the Food and Drug Administration for safety or efficacy;

(4) those who are pregnant or nursing should consult their healthcare provider before use; and

(5) if the product is an inhalable cannabinoid hemp product, a warning stating that smoking or vaporizing is hazardous to your health.

(g) No information required to be listed on cannabinoid hemp product labeling or packaging in accordance with this section shall be smaller than 4.5-point font, and the information required by

subparagraphs (a)(3)(i) through (iii) and paragraph (f)(2) of this section shall be bolded and at least one font sized larger than other text required to be listed on the product label.

#### Section 1005.10 Laboratory testing requirements for cannabinoid hemp

(a) For purposes of this Section, the following terms shall have the following meanings:

(1) “Accreditation body” means an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.

(2) “Scope of accreditation” means a document issued by an accreditation body that attests to the laboratory’s competence to carry out specific testing and analysis.

(3) “Testing laboratory” means an independent, third-party laboratory, contracted by a cannabinoid hemp processor to test cannabinoid hemp products.

(b) To be recognized as a testing laboratory for purposes of testing cannabinoid hemp products as required by this Part, a laboratory must either be approved to test medical marijuana pursuant to Section 55-2.15 of this Title, or meet all of the following minimum requirements:

(1) maintain ISO/IEC 17025 accreditation for the premises and for the testing of one or more of the following:

(i) Cannabinoids;

(ii) Heavy metals;

(iii) Microbial impurities;

(iv) Mycotoxins;

(v) Residual pesticides;

(vi) Residual solvents and processing chemicals; or

(vii) If tested, terpenoids.

(2) maintain a valid scope of accreditation, issued by an accreditation body, that attests to the laboratory's competence to perform testing of one or more analytes listed in subdivision (b)(1) of this section.

(3) maintain method validation reports for all testing performed; and

(4) maintain standard operating procedures for the sampling of cannabinoid hemp products.

(c) Cannabinoid hemp processors shall retain, and make available to the department upon request, all records associated with their testing laboratory's ISO/IEC 17025 accreditation, scope of accreditation, method validation reports and standard operating procedures for the sampling of cannabinoid hemp products, as required by this section.

(d) Cannabinoid hemp products shall be considered adulterated and shall not be sold within New York State, if contaminants are detected at levels greater than provided for by the department in this Part or issued in further guidance.

(e) The department shall have the ability to impose additional testing requirements including but not limited to, testing for additional analytes, setting stricter contaminant limits and mandating the use of specific sampling methodologies per lot or batch manufactured.

(f) Pesticide Limits. The following list of contaminants does not constitute authorization to use or apply any of the following during hemp cultivation or processing. If a pesticide is identified that is not listed here, the method limit of quantitation should be considered the maximum residue level for the unlisted pesticide:

1. Abamectin, 300 parts per billion.
2. Acephate, 3,000 parts per billion.
3. Acequinocyl, 2,000 parts per billion.
4. Acetamiprid, 3,000 parts per billion.
5. Aldicarb, 100 parts per billion.

6. Azoxystrobin, 3,000 parts per billion.
7. Bifenazate, 3,000 parts per billion.
8. Bifenthrin, 500 parts per billion.
9. Boscalid, 3,000 parts per billion.
10. Captan, 3,000 parts per billion.
11. Carbaryl, 500 parts per billion.
12. Carbofuran, 100 parts per billion.
13. Chlorantraniliprole, 3,000 parts per billion.
14. Chlordane, 100 parts per billion.
15. Chlorfenapyr, 100 parts per billion.
16. Chloromequat chloride, 3,000 parts per billion
17. Chlorpyrifos, 100 parts per billion.
18. Clofentezine, 500 parts per billion.
19. Coumaphos, 100 parts per billion.
20. Cyfluthrin, 1,000 parts per billion.
21. Cypermethrin, 1,000 parts per billion.
22. Daminozide, 100 parts per billion.
23. DDVP (Dichlorvos), 100 parts per billion.
24. Diazinon, 200 parts per billion.
25. Dimethoate, 100 parts per billion.
26. Dimethomorph, 3,000 parts per billion.
27. Ethoprop(hos), 100 parts per billion.
28. Etofenprox, 100 parts per billion.



29. Etoxazole, 1,500 parts per billion.
30. Fenhexamid, 3,000 parts per billion.
31. Fenoxycarb, 100 parts per billion.
32. Fenpyroximate, 2,000 parts per billion.
33. Fipronil, 100 parts per billion.
34. Flonicamid, 2,000 parts per billion.
35. Fludioxonil, 3,000 parts per billion.
36. Hexythiazox, 2,000 parts per billion.
37. Imazalil, 100 parts per billion.
38. Imidacloprid, 3,000 parts per billion.
39. Kresoxim-methyl, 1,000 parts per billion.
40. Malathion, 2,000 parts per billion.
41. Metalaxyl, 3,000 parts per billion.
42. Methiocarb, 100 parts per billion.
43. Methomyl, 100 parts per billion.
44. Methyl parathion, 100 parts per billion.
45. Mevinphos, 100 parts per billion.
46. Myclobutanil, 3,000 parts per billion.
47. Naled, 500 parts per billion.
48. Oxamyl, 500 parts per billion.
49. Paclobutrazol, 100 parts per billion.
50. Pentachloronitrobenzene, 200 parts per billion.
51. Permethrin, 1,000 parts per billion.

52. Phosmet, 200 parts per billion.
53. Piperonyl butoxide, 3,000 parts per billion.
54. Prallethrin, 400 parts per billion.
55. Propiconazole, 1,000 parts per billion.
56. Propoxur, 100 parts per billion.
57. Pyrethrins, 1,000 parts per billion.
58. Pyridaben, 3,000 parts per billion.
59. Spinetoram, 3,000 parts per billion.
60. Spinosad A & D, 3,000 parts per billion.
61. Spiromesifen, 3,000 parts per billion.
62. Spirotetramat, 3,000 parts per billion.
63. Spiroxamine, 100 parts per billion.
64. Tebuconazole, 1,000 parts per billion.
65. Thiacloprid, 100 parts per billion.
66. Thiamethoxam, 1,000 parts per billion.
67. Trifloxystrobin, 3,000 parts per billion.

(g) Residual Solvent Limits.

1. 1,2-Dichloroethane, 5 parts per million
2. 1,1-Dichloroethane, 8 parts per million
3. Acetone, 5,000 parts per million
4. Acetonitrile, 410 parts per million
5. Benzene, 2 parts per million

6. Butane, 2,000 parts per million
7. Chloroform, 60 parts per million
8. Ethanol, 5,000 parts per million
9. Ethyl Acetate, 5,000 parts per million
10. Ethyl Ether, 5,000 parts per million
11. Ethylene Oxide, 5 parts per million
12. Heptane, 5,000 parts per million
13. Hexane, 290 parts per million
14. Isopropyl Alcohol, 5,000 parts per million
15. Methanol, 3,000 parts per million
16. Methylene Chloride, 600 parts per million
17. Pentane, 5,000 parts per million
18. Propane, 5,000 parts per million
19. Toluene, 890 parts per million
20. Trichloroethylene (1,1,2-Trichloroethene), 80 parts per million
21. Xylenes, Total (ortho-, meta-, para-), 2170 parts per million

(h) Metals Limits.

1. Cadmium, 0.5 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.2 micrograms/gram for cannabinoid hemp products intended for inhalation.
2. Lead, 1.0 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.5 micrograms/gram for cannabinoid hemp products intended for inhalation.

3. Arsenic, 1.5 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.2 micrograms/gram for cannabinoid hemp products intended for inhalation.

4. Mercury, 1.5 micrograms/gram for cannabinoid hemp products intended for ingestion. 0.1 micrograms/gram for cannabinoid hemp products intended for inhalation.

(i) Biological Limits.

1. Shiga toxin-producing Escherichia coli (STEC E. coli) and other pathogenic E. coli, none present detected in 1 gram.

2. Salmonella, none present.

3. Total plate count for aerobic bacteria,  $<10^4$  CFUs/gram.

4. Total yeast and mold,  $<10^3$  CFUs/gram.

(j) Mycotoxin Limits.

1. Total Aflatoxin (B1, B2, G1, G2), 20 parts per billion.

2. Ochratoxin A, 20 parts per billion.

(k) Cannabinoid Limits. The total  $\Delta^9$ -Tetrahydrocannabinol concentration for cannabinoid hemp products shall not exceed three-tenths of a percent (0.3%). If a cannabinoid hemp product fails, the processor may elect to re-extract the failing batch to reduce the total  $\Delta^9$ -Tetrahydrocannabinol of the batch to not more than three-tenths of a percent (0.3%) total  $\Delta^9$ -Tetrahydrocannabinol. If the re-extracted batch still exceeds the three-tenths of a percent (0.3%) total  $\Delta^9$ -Tetrahydrocannabinol the processor shall destroy the batch in compliance with subdivision (d) of section 1005.7 of this Part.

(l) If a cannabinoid hemp product is found to contain levels of any pathogen, toxicant, residual solvent, metal, or pesticide not enumerated in this section or by New York State law, then the product shall not be sold in New York State.

#### Section 1005.11 Requirements for cannabinoid hemp retailers

(a) Cannabinoid hemp retailers shall only sell cannabinoid hemp products manufactured, packaged, labeled and tested in accordance with this Part.

(b) Cannabinoid hemp retailers shall not offer or sell any cannabinoid hemp product clearly labeled or advertised for the purpose of smoking, or in the form of a cigarette, cigar, or pre-roll, or packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes. Retailers shall have sufficient safeguards in place to verify that an individual presenting or submitting proof of age for an inhalable cannabinoid hemp product or flower product matches the identification and is 21 years of age or older.

(c) Cannabinoid hemp retailers shall post, visible to consumers, any and all signs or posted placards required by the department, including posting of the cannabinoid hemp retail license issued by the department, in a conspicuous location on the premises of each retail location.

(d) Cannabinoid hemp products shall be displayed in a manner that distinguishes them from non-cannabinoid hemp products, to aide consumers in locating cannabinoid hemp products and avoid accidental purchase or consumption.

(e) Cannabinoid hemp retailers shall maintain sufficient records of where cannabinoid hemp products were purchased from for the license period, including the name of the cannabinoid hemp processor if applicable, and the wholesaler or permitted distributor if applicable.

(f) The department may inspect any retail location offering cannabinoid hemp products. This inspection may include taking samples of cannabinoid hemp products to ensure compliance with all the requirements of this Part.

#### Section 1005.12 Advertising requirements

(a) An advertisement for a cannabinoid hemp product, cannabinoid hemp processor or cannabinoid hemp retailer shall not:

(i) make any false or misleading claims or statements;

(ii) contain claims that cannabinoid hemp or a cannabinoid hemp product can, or is intended to, diagnose, cure, mitigate, treat, or prevent disease;

(iii) lead a reasonable person to believe that a cannabinoid hemp product is cannabis, marihuana, medical cannabis, or medical marihuana, or that a licensee is authorized to sell or dispense cannabis, marihuana, medical cannabis, or medical marihuana, as those terms are defined in Section 3 of the Cannabis Law and Article 33 of the Public Health Law;

(iv) have the purpose or effect of targeting or appealing to anyone under 21 years of age for inhalable cannabinoid hemp products or flower product. The use of images of children or minors consuming the product and the use of words, a design or brand that resembles a product that is commonly associated with children or minors or marketed to children or minors, is prohibited.

#### Section 1005.13 New York Hemp Product

(a) A New York Hemp Product is a cannabinoid hemp product exclusively grown in New York State and processed in New York State by processors that are licensed under this Part and that demonstrate compliance with all requirements enumerated by the department;

(b) The department may establish standards and requirements above and beyond those established in this Part and use such standards and requirements to certify products as New York Hemp Product.

(c) The department may revoke a cannabinoid hemp product's status as certified New York Hemp Product, without a hearing, if it has reason to believe that such product no longer meets one or more of the standards or requirements established by the department.

(d) No cannabinoid hemp product sold in New York state may use the term "New York Hemp Product" or hold itself out as being New York Hemp Product, or approved or certified by the department in any way, unless such product has been certified by the department pursuant to this section, in which case the cannabinoid hemp processor and cannabinoid hemp retailer may

portray such product(s) as being certified New York Hemp Product. A violation of this subdivision constitutes grounds for suspension or revocation of a license.

#### Section 1005.14 General prohibitions

(a) No licensee shall engage in any activity relating to the processing, packaging, labeling manufacturing, extracting, distributing, selling or laboratory testing of cannabinoid hemp extract or cannabinoid hemp that does not comply with the requirements of Article 33-B of the Public Health Law and this Part.

(b) No person shall extract hemp extract or manufacture cannabinoid hemp products in New York State unless licensed to engage in such activity by the department or otherwise authorized by the United States food and drug administration.

(c) Hemp extract shall be manufactured into cannabinoid hemp product before being offered for retail sale and shall not be distributed or sold directly to consumers within the state.

(d) No cannabinoid hemp product shall be distributed or offered for retail sale in New York State unless:

(1) it complies with the processing, packaging, labeling and testing requirements pursuant to sections 1005.8, 1005.9 and 1005.10 of this Part; and

(2) is sold by a cannabinoid hemp retailer licensed under this Part;



(e) No person shall transport hemp extract within the state, unless:

(1) it is in a fully enclosed vehicle or container; and

(2) accompanied by a manifest or proof of ownership, documenting the name, physical address, lot or batch number, certificate of analysis and license number of the originating licensed cultivator or processor, and the name and physical address of the recipient of the delivery when transporting between non-adjointing facilities. When hemp extract is being transported to a laboratory for testing, a certificate of analysis is not required to accompany the shipment.

(f) Hemp extract shall not be shipped or transported into New York State unless:

(1) it is in a fully enclosed vehicle or container;

(2) accompanied by proof of origin with a hemp cultivation or processor license number, or equivalent, from the jurisdiction of origin; and

(3) accompanied by a certificate of analysis showing that the hemp extract has a total  $\Delta 9$ -Tetrahydrocannabinol of no more than three tenths of a percent (0.3%).

(g) No person shall distribute cannabinoid hemp products manufactured out of state, to a cannabinoid hemp retailer within New York State, unless permitted pursuant to section 1005.18 of this Part.

#### Section 1005.15 Cannabinoid hemp processor prohibitions

(a) No cannabinoid hemp processor may transfer a license issued under this Part without prior written approval of the department.

(b) No cannabinoid hemp processor shall manufacture a cannabinoid hemp product that is a potentially hazardous food, as defined by Section 14-1.31 of this Title.

(c) No cannabinoid hemp processor may conduct final product testing for the licensee's own products to meet the testing requirements of Section 1005.10 of this Part. Nothing in this Part prohibits a cannabinoid hemp processor from performing internal testing for research and product development or for quality assurance prior to final product testing by a third-party laboratory.

(d) No cannabinoid hemp processor may sell cannabinoid hemp products to consumers for final retail sale without first obtaining a cannabinoid hemp retail license.

(e) No cannabinoid hemp processor shall sell hemp extract to anyone in New York State, unless such person is licensed as a cannabinoid hemp processor under this Part or registered as a registered organization under Section 3365 of the Public Health Law.

#### Section 1005.16 Cannabinoid hemp retailer prohibitions

(a) No cannabinoid hemp retailer shall offer or sell cannabinoid hemp products in the form of an inhalable cannabinoid hemp product or flower product to anyone under 21 years of age.

(b) No cannabinoid hemp retailer shall sell a cannabinoid hemp product that is a potentially hazardous food, as defined by Section 14-1.31 of this Title.

(c) Cannabinoid hemp retailers shall only offer and sell cannabinoid hemp products that meet all of the standards and requirements of Sections 1005.8, 1005.9 and 1005.10 of this Part.

(d) Cannabinoid hemp retailers shall not offer or sell any cannabinoid hemp product to be added to food or other consumable products at the point of sale.

#### Section 1005.17 Penalties

(a) Licensees under this Part shall comply with all applicable laws, rules and regulations as it relates to such licensure.

(b) Failure to comply with a requirement of Article 33-b of the Public Health Law or this Part may be punishable by a civil penalty, as follows:

(i) a fine of up to \$1,000 for a first violation;

(ii) a fine up to \$5,000 for a second violation within three-years; or

(iii) a fine up to \$10,000 for a third violation and each subsequent violation thereafter, within a three-year period.

(c) Where a licensee willfully violates, refuses or neglects to comply with one or more sections of this Part, the department may limit, suspend, revoke or annul a license after providing notice and an opportunity for a hearing to the licensee. However, a license may be temporarily limited, suspended, revoked or annulled without a hearing for a period not to exceed 30-days, upon notice to the licensee, following a finding by the department that the public health, safety or welfare is in imminent danger.

(d) A licensee who negligently violates this Part three times in a five-year period shall be ineligible to process or sell cannabinoid hemp for a period of five years beginning on the date of the third violation. The department, for good cause shown, may choose to impose a lesser penalty.

#### Section 1005.18 Cannabinoid hemp permits

(a) The department may issue cannabinoid permits expressly authorizing a permittee to conduct one or more of the following activities:

- (1) distribute cannabinoid hemp products manufactured out of state, to cannabinoid hemp retailers within New York State;
- (2) deliver cannabinoid hemp products from a cannabinoid hemp retailer to consumers;
- (3) sell at retail cannabinoid hemp products for a limited duration;
- (4) continue operations for persons holding a valid CBD processor research partnership agreement with the New York State Department of Agriculture and Markets pursuant to Article 29-A of the New York State Agriculture and Markets Law;
- (5) any other activity as determined by the commissioner.

(b) Applicants for a cannabinoid hemp permit must apply on a form prescribed by the department and submit a \$100 application fee and permit fee as may be set by the department.

(c) Permits issued pursuant to this section shall be valid for one year from the date of issuance, unless the department prescribes a shorter time period for expiration.

#### Section 1005.19 Severability.

The provisions of this Part are severable. If any provision of this Part is found to be invalid, or if any application of this Part to any person or circumstance is found to be invalid, the invalidity shall not affect any other provisions or applications which can be given effect without the invalid provision or application.

Section 1005.20 Incorporation by reference.

The provisions of the Code of Federal Regulations which have been incorporated by reference in this Subpart have been filed in the Office of the Secretary of State of the State of New York, the publication so filed being the booklet entitled: Code of Federal Regulations, Title 21, Parts 101, 111, and 117, revised as of April 1, 2012, June 25, 2007, and January 1, 2019 respectively, published by the Office of the Federal Register, National Archives and Records Administration. The regulations incorporated by reference may be examined at the Records Access Office, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237 or can be directly obtained from the Superintendent of Documents, US Government Printing Office, Washington, D.C. 20402.

Section 1005.21 Effective date

(a) The provisions of this Part are effective upon publication in the State Register; provided, however, that sections 1005.9 and 1005.10 shall not become effective until November 1, 2021.

(b) Notwithstanding subdivision (a) of this section, a licensed cannabinoid hemp retailer may continue to possess, transport, and sell cannabinoid hemp products in the retailer's inventory before the effective date of this Part, unless the cannabinoid hemp product:

(1) is unsafe for consumption based on the presence or quantity of heavy metals, pesticides, harmful microorganisms, or residual solvents;

- (2) has a  $\Delta$ -9 tetrahydrocannabinol concentration of more than 0.3 percent;
- (3) is a flower product clearly labeled or advertised for the purpose of smoking or in the form of a cigarette, cigar or pre-roll or otherwise packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes; or
- (4) contains or was manufactured with  $\Delta$ 8-tetrahydrocannabinol or  $\Delta$ 10-tetrahydrocannabinol created through isomerization.

## **Regulatory Impact Statement**

### **Statutory Authority:**

The Commissioner of Health is authorized pursuant to Section 3398-a of the Public Health Law (PHL), to promulgate rules and regulations necessary to effectuate the provisions of Article 33-B of the PHL.

### **Legislative Objectives:**

The legislative objective of Article 33-B of the PHL is to comprehensively regulate the processing and sale of cannabinoid hemp products in New York State. The regulation of cannabinoid hemp products will promote this objective and public health by instituting consumer protections ensuring products are manufactured, tested and labeled to comparative standards of similar products in the dietary supplement, food and cannabis industries. Further, the regulations will spur economic development of the New York States domestic hemp industry by providing clear rules and expectations of how and what type of cannabinoid hemp products can be sold.

### **Needs and Benefits:**

The Federal Farm Bill of 2018 created a legal pathway for hemp cultivation by removing hemp, a subset of the *Cannabis Sativa L.* plant species, with less than 0.3% Δ9-Tetrahydrocannabinol from the Controlled Substance Act. Farmers from across the country began growing hemp, an extremely versatile crop that has a reported 25,000 different uses including in textiles, automotive parts, furniture, fuel, food and beverages, paper, construction materials and personal care items.



Over the past several years, the expansion of hemp cultivation has primarily been driven by a chemical component found in the hemp plant called cannabidiol or “CBD.” CBD is one of many cannabinoids found in hemp and has become increasingly popular.

Although there has been a rapid increase in the use of cannabinoid hemp products, the Federal government has not implemented a regulatory system to effectively control the quality of products on the market. In this absence, unscrupulous actors have entered the market and sold cannabinoid hemp products that do not meet the quality control standards common in the established supplement, food and cannabis industries. Reports of cannabinoid hemp products that do not contain any cannabinoids at all or are contaminated with harmful toxins and pesticides are common.

The proposed regulations are intended to organize and legitimize the cannabinoid market in New York State by creating a license framework for cannabinoid hemp processors and retailers and by establishing quality control standards that all cannabinoid hemp products must meet or exceed. To accomplish this, the regulations propose the following:

1. License and hold cannabinoid hemp processors to federally-established standards of good manufacturing practices (GMP) at the dietary supplement or food standard depending on the finished product.
2. Require packaging and labeling standards that accurately inform the consumer of the quantity of cannabinoids in the product, include a link or QR code to the third-party tests results, and provide appropriate warnings of the potential risks associated with their consumption.
3. Impose laboratory testing requirements on all lots of cannabinoid hemp products, testing for cannabinoid profile, heavy metals, microbials, mycotoxins, pesticides and residual solvents.

4. License and hold retailers accountable to only sell approved forms of cannabinoid hemp products purchased from sources that manufacture to the standards of the program and restrict sales of inhalable cannabinoid hemp products to minors.
5. Authorize the Department to oversee and enforce against cannabinoid hemp products in the marketplace not meeting New York's standards and to take appropriate action to protect public health and impose consumer protections.

**Costs:**

**Costs to the Regulated Entity:**

The proposed regulations impose costs on licensees. Cannabinoid hemp processors will be required to pay an application fee of \$1,000 or \$500 and a license fee of either \$3,500 or \$1,000, depending on whether the licensee is authorized to extract hemp extract in addition to manufacturing cannabinoid hemp products. In addition, cannabinoid hemp processor licensees will be required to manufacture cannabinoid hemp products for human consumption to dietary supplement or food standards complying with good manufacturing processes and maintaining third-party audit documenting this standard. All cannabinoid hemp products are required to be tested by a third-party accredited laboratory and products must be packaged and labeled in a manner that is consistent with public health best practices. Finally, cannabinoid hemp retailers will be required to pay a \$300 license fee for each location where cannabinoid hemp products are sold.

**Costs to Local Government:**

The proposed regulations do not require local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

**Costs to the Department of Health:**

The proposed regulations will incur costs to the Department to develop a licensing system to review and approve applications from potential licensees, maintain the administrative and customer service aspects of the program, and inspect and enforce licensees to maintain the quality assurance standards of the program.

**Local Government Mandates:**

These proposed regulations do not impose any new programs, services, duties or responsibilities on local government.

**Paperwork:**

The proposed regulations will impose new requirements to track and maintain licensing and pertinent records of the regulated activities established in the proposed regulations. Licensees will need to retain all required records for a minimum of five years.

**Duplication:**

No relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with these proposed regulations.

**Alternatives:**

The Department is statutorily obligated to promulgate regulations pursuant to Section 3398-a of the Public Health Law. The Department considered not regulating inhalable products differently, including not setting separate age limits. However, the Department ultimately decided to

establish additional restrictions on inhalable products to deter smoking and youth-use. In addition, the Department could have adopted the regulations as initially proposed; however, in response to public comments the Department has revised the regulations to address a number of concerns raised by stakeholders. These changes include but are not limited to amending what is required to be included on cannabinoid hemp product packaging and labeling, amending the testing limits for a number of different analytes and lowering the license fees for processors to make the license fee more attainable for small businesses. Additionally, to address changes in the recently enacted Marijuana Regulation & Taxation Act, the regulations were modified to permit the sale of cannabinoid hemp flower products, provided such products are not marketed or advertised for smoking.

#### **Federal Standards:**

The 2018 Farm Bill directed the United States Department of Agriculture (USDA) to establish a national regulatory framework for hemp cultivation in the United States. The Food and Drug Administration (FDA) has authority to regulate cannabinoids. USDA established the U.S. Domestic Hemp Production Program through an interim final rule; however, the FDA is just beginning the rulemaking process and therefore, there are currently no federal standards for cannabinoid hemp processors or cannabinoid hemp retailers.

#### **Compliance Schedule:**

The regulations shall be effective upon publication of the Notice of Adoption in the State Register. However, section 1005.9 governing packaging and labeling of cannabinoid hemp products and section 1005.10 governing laboratory testing requirements, shall not become

effective until November 1, 2021. This will afford regulated entities additional time to come into compliance with the regulatory requirements.

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## **Regulatory Flexibility Analysis for Small Businesses and Local Governments**

### **Effect on Small Business and Local Government:**

The proposed regulations require cannabinoid hemp processors to manufacture products to good manufacturing practices (GMP) found in the dietary supplement or food industries, test products at accredited third-party laboratories, and package and label products to promote consumer awareness and protect the integrity of the product. Many of these same standards were already imposed by the Department of Agriculture and Markets Industrial Hemp Research Pilot Program which, prior to Chapter 1 of the Laws of 2020, oversaw cannabinoid processors in New York State. Due to the confusion of the regulatory status of cannabinoid hemp products at the federal level, products have been left in an unregulated status. These regulations are intended to bring cannabinoid hemp products on par with other standards already developed in similar industries and is not meant to disadvantage small businesses. Many operators in the hemp industry are looking for regulations to legitimize and standardize the neophyte industry.

The requirements placed on cannabinoid hemp retailers are less demanding and include licensure, record keeping, age verification and restrictions on the forms of cannabinoid hemp products which may be sold.

Large and small businesses that are creating or selling products that do not meet basic consumer protections and refuse to come into compliance will be penalized and have their products removed from the market.

### **Compliance Requirements:**

Small businesses that apply as a cannabinoid hemp processor must meet third-party GMP certification within six months of approval of the application to obtain licensure, must test products at an accredited third-party lab and package, and must label products in conformance

with the requirements of the regulations. A small business that chooses to apply as a cannabinoid hemp retailer must comply with the proposed regulations including licensure, record keeping, age verification and restrictions on the forms of cannabinoid hemp products which may be offered for retail sale.

**Professional Services:**

The proposed regulations create a need for cannabinoid hemp processors to seek a third-party audit to certify their manufacturing process to good manufacturing practices (GMP) in accordance with Parts 101, 111 or 117 of Title 21 Code of Federal Regulations, depending on the final product.

**Compliance Costs:**

The proposed regulations will impose a cost to cannabinoid hemp processor licensee's seeking third-party GMP certification. Certification is based on the size of the facility and complexity of the manufacturing process. Several businesses will have to change operations to meet the higher standard to protect public health and consumer safety. Application and license fees in the amount of \$1,000 and \$3,500 respectively will be required for cannabinoid hemp processors, while a \$500 application fee and \$1,000 licensee fee will be required for those only manufacturing cannabinoid hemp. Retailers must pay a \$300 license fee per location.

**Cost to State and Local Governments:**

There are no direct costs to Local Governments associated with the proposed regulations as the State will be incurring the costs of regulatory oversight and inspection of licensees.

**Economic and Technological Feasibility:**

This proposed regulation is economically and technically feasible, as these regulations mirror similar requirements that already exist in the dietary supplement, food and cannabis industries.

**Minimizing Adverse Economic Impact:**

The impact of this regulation is expected to be minimal for existing CBD processors operating in compliance under Agriculture and Markets Industrial Hemp Research Pilot Program which already imposed many of the same standards as the proposed regulations. The Department understands the current ambiguity in the cannabinoid hemp market nationally and is willing to work with entities to reach compliance.

**Small Business and Local Government Participation:**

The proposed regulations include recommendations from the hemp industry including the New York Cannabis Grower and Processor Association (NYCGPA), the Hemp Round Table and the New York State Farm Bureau. The Department will proactively contact existing research partners from the current pilot program to provide information on where they may locate the proposed regulations, how to provide public comments and work with them to transition over into the new program.



## Rural Area Flexibility Analysis

### Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<https://www.census.gov/quickfacts/>).

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County St.	Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
Schenectady County		

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

**Compliance Requirements:**

Cannabinoid hemp processors and cannabinoid hemp retailers that are located in rural areas will be required to apply to the Department for licensure. Once licensed, cannabinoid hemp processors in rural areas will be required to extract hemp extract and/or manufacture cannabinoid hemp products using Good Manufacturing Practices (GMP) and to the standards set forth in these regulations, including requirements on packaging and labeling, product testing, and advertising. Cannabinoid hemp retailers in rural areas will be required to only sell cannabinoid hemp products meeting all of the standards set forth in these regulations, including restrictions on certain forms of administration and only sell inhalable cannabinoid hemp products to individuals 21 year of age or older.

**Professional Services:**

Cannabinoid hemp processors and cannabinoid hemp retailers in rural areas are expected to use existing staff to comply with the requirements of this regulation. Additionally, cannabinoid hemp processors are required to obtain a qualified third-party Good Manufacturing Practices (GMP) audit and will need to utilize independent third-party laboratories.

**Compliance Costs:**

The proposed regulations impose costs on rural area licensees. Cannabinoid hemp processors in rural areas will be required to pay an application fee of \$1,000 or \$500 and a license fee of either \$3,500 or \$1,000, depending on whether the licensee is authorized to extract hemp extract in addition to manufacturing cannabinoid hemp products. In addition, rural area cannabinoid hemp processors will be required to manufacture cannabinoid hemp products for human consumption to dietary supplement or food standards complying with good manufacturing processes and maintaining third-party audit documenting this standard. All cannabinoid hemp products are required to be tested by a third-party accredited laboratory and products must be packaged and labeled in a manner that is consistent with public health best practices. Finally, cannabinoid hemp retailers in rural areas will be required to pay a \$300 license fee for each location where cannabinoid hemp products are sold.

**Minimizing Adverse Impact:**

The Department is statutorily obligated to promulgate regulations pursuant to Section 3398-a of the Public Health Law so no alternatives to the proposed regulations were considered. The impact of this regulation is expected to be minimal for existing CBD processors operating in compliance under Agriculture and Markets Industrial Hemp Research Pilot Program which already imposed many of the same standards as the proposed regulations.

**Rural Area Input:**

The proposed regulations include recommendations from the hemp industry including the New York Cannabis Grower and Processor Association (NYCGPA) which represents hemp growers and processors throughout the State, including rural areas.

### **Statement in Lieu of Job Impact Statement**

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the amendment, that it will not have an adverse impact on jobs and employment opportunities.

## Summary of Assessment of Public Comment

The New York State Department of Health (the “Department”) received comments from hundreds of stakeholders in response to the proposed regulation adding a new Part 1005 to Title 10 of the Code, Rules and Regulations of the State of New York relating to cannabinoid hemp. Public comments were received from industry stakeholders, including cannabinoid hemp growers, processors, retailers and laboratories, as well as from the general public, cannabinoid hemp consumers, elected officials, and industry associations. The comments covered almost every aspect of the proposed regulation, including the manufacturing, packaging and labeling, and laboratory testing requirements, as well as the application process, allowable forms of cannabinoid hemp products and the transportation of cannabinoid hemp within New York State.

The largest number of comments were concerning the types of cannabinoid hemp products allowed to be sold. More specifically, commenters requested that cannabinoid hemp flower products, suppositories, transdermal patches and inhalers be authorized for retail sale to consumers. In addition, commenters requested amendments to the packaging and labeling provisions concerning the requirement to list all cannabinoids within products, including the THC content. Additional comments questioned the Department’s ability to impose a milligram per THC cap for cannabinoid hemp products while several commenters requested the Department modify testing requirements to either add or remove listed analytes or modify threshold limits.

As a result of these public comments, the Department has amended the proposed regulation and is issuing a Notice of Revised Rulemaking.

## Assessment of Public Comment

The New York State Department of Health (Department) received hundreds of public comments in response to the proposed rulemaking adding a new Part 1005 to Title 10 of the Code, Rules and Regulations of the State of New York relating to cannabinoid hemp. Public comments were received from industry stakeholders, including cannabinoid hemp growers, processors, retailers and laboratories, as well as from the general public, cannabinoid hemp consumers, elected officials, and industry associations. Many comments were received concerning manufacturing standards, packaging and labeling requirements, laboratory testing, non-permitted forms of cannabinoid hemp, and the transportation of cannabinoid hemp products. The cannabinoid hemp processor and retailer applications, fees associated with these applications, and record keeping requirements on cannabinoid hemp processors and retailers, also elicited numerous comments. Based on the public comments, the Department has made revisions to the proposed regulations. The comments and the Department's response are summarized below.

**COMMENT:** Comments were received requesting that words included in the definitions listed in section 1005.1 be capitalized throughout the proposed regulation.

**RESPONSE:** Due to established standards for how New York State rules and regulations are drafted, no changes to the proposed regulation were made as a result of this comment.

**COMMENT:** Comments were received suggesting changes to the definitions of “broad spectrum” and “full spectrum” to better align with how the terms are used in the industry and to account for the limitations in the removal of  $\Delta 9$ -Tetrahydrocannabinol from broad spectrum products. Commenters also suggested adding THCA to the definitions of these terms.

**RESPONSE:** The Department has revised the definition for “broad spectrum” and “full-spectrum” to better align with the industry’s understanding and usage of the terms. Additionally, changes were made acknowledging that the complete removal of  $\Delta$ 9-Tetrahydrocannabinol is not practical for “broad spectrum” products and instead including a corresponding threshold of THC. The proposed regulation already contemplates THCA in the definition of “total  $\Delta$ 9-Tetrahydrocannabinol.”

**COMMENT:** Comments were received suggesting modifications of the definition of “cannabinoid hemp product” to more explicitly exclude hemp grain, seed-derived products and microgreens/leaves which may contain trace levels of cannabinoids. Additionally, commenters suggested removing “hemp-derived terpenes” from the definition of a cannabinoid hemp product.

**RESPONSE:** The proposed regulation already contemplates the exclusion of hemp grain and hemp-seed derived products through the statutory definitions of “used for human consumption” and “hemp extract” in Article 33-B of the Public Health Law (PHL). To the extent that further clarification is needed, the Department can issue corresponding guidance. Additionally, the Department maintains the inclusion of hemp-derived terpenes in the definition of cannabinoid hemp product to better regulate this rapidly developing aspect of the market. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Commenters suggested removing a number of minor cannabinoids listed under the definition of “cannabinoids” because reliable testing methods have not been developed to measure all of the cannabinoids currently listed. Further, commenters suggested defining cannabinoids more broadly to include “hemp-derived” cannabinoids.

**RESPONSE:** The definition of cannabinoids does not mandate testing of the cannabinoids listed under the definition. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Comments were received asking whether the definition of “cannabinoid hemp retailer” includes businesses located outside of New York State selling products online to New York consumers.

**RESPONSE:** Retailers located outside of New York State selling cannabinoid hemp products online to consumers in New York State are required to obtain a cannabinoid hemp retail license. Requiring out-of-state entities to obtain a cannabinoid hemp retail license is necessary to ensure all products sold in New York meet the requirements of the Cannabinoid Hemp Program, and provides parity in the treatment of in-state and out-of-state businesses. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Comments were received seeking clarification as to whether the definition of a “cannabinoid hemp processor” only applies to processors located in New York State. Additionally, commenters asked whether de minimis mixing or packing activities that do not significantly affect the final cannabinoid content of a product would still require a cannabinoid hemp processor license.

**RESPONSE:** The Department has modified the proposed regulation to clarify that only processors located in New York State require a cannabinoid hemp processor license. With respect to licensing processors who only undertake limited mixing or packing activities, the Department maintains licensure is required for these activities since the risk of product



contamination exists throughout the product development supply-chain. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Comments were received asking to modify the definitions of “distillate” and “isolate” to more appropriately conform to how such terms are used by participants in the industry.

**RESPONSE:** The regulation was revised to incorporate technical changes to the definitions of “distillate” and “isolate” in response to these comments.

**COMMENT:** Commenters suggested modifications to the definition of “hemp extract” to remove the Department’s ability to set a  $\Delta$ 9-Tetrahydrocannabinol limit more restrictive than federal law. Additionally, commenters requested that the definition not exclude products that are Generally Recognized as Safe (GRAS), as the United States Food and Drug Administration (FDA) does not regulate hemp extract and the exclusion could preempt cannabinoids that in the future are determined to be GRAS.

**RESPONSE:** PHL § 3398(5) authorizes the Department to set the  $\Delta$ 9-Tetrahydrocannabinol level of hemp extract in regulation. Pursuant to that authority, section 1005.7(b) of the proposed regulation sets the limit at three percent (3%) THC for intermediate sales of hemp extract. The exclusion of GRAS hemp products from the definition of hemp extract is intended to ensure hemp-derived food products such as hulled hemp seed are not regulated under the Cannabinoid Hemp Program. The Department would consider amending the definition in future rulemaking should the FDA begin providing regulatory oversight. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Comments were received requesting that the definition of “flower product” not include hemp flower used for food, including hemp leaf, microgreens or sprouts.

**RESPONSE:** The revised regulation clarifies that flower product does not include hemp sold as a food, such as hemp leaves, microgreens or sprouts. These products are not sold for their cannabinoid content and are therefore outside the regulatory authority provided by Article 33-B of the Public Health Law.

**COMMENT:** Commenters stated that the definitions of “hemp” and “hemp extract” do not exclude medical marijuana. The commenters noted that as written, the regulation will apply to both the hemp requirements herein and to medical marijuana products.

**RESPONSE:** PHL § 3302(21) defines “Medical Marijuana” to exclude “hemp.” While both hemp and medical marijuana are derived from the cannabis sativa plant, the PHL establishes two separate and distinct programs, which the proposed regulation accurately reflect. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Comments were received suggesting the modification of the definition of “total  $\Delta$ 9-Tetrahydrocannabinol concentration” to align with the definition in the 2018 Agriculture Improvement Act (Farm Bill), suggesting that the current definition will exclude post-decarboxylation methods of testing.

**RESPONSE:** The 2018 Farm Bill pertains to the cultivation of hemp, while Article 33-B of the PHL and the proposed regulation apply to hemp extract and cannabinoid hemp products. The definition of “total  $\Delta$ 9-Tetrahydrocannabinol concentration” does not limit the testing methods that may be used to test cannabinoid hemp products. No changes were made to the proposed regulation as a result of this comment.

**COMMENT:** Commenters suggested amending the definition of “used for human consumption” to exclude products that are applied topically.

**RESPONSE:** Public Health Law § 3398(3) defines “used for human consumption” to include products intended by the manufacturer or distributor to be used in, on, or by the human body for its cannabinoid content. Accordingly, the definition in the proposed regulation includes products applied topically and is consistent with the requirements of statute. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Commenters requested more detail regarding acceptable third-party Good Manufacturing Practices (GMP) audits, including what certifications will be accepted. The Department also received comments requesting the creation of an application or Request for Proposal (RFP) process for GMP auditors and asked whether the Department plans to make available a list of approved auditors.

**RESPONSE:** The Department intends to issue guidance regarding third-party GMP audits and the Department’s acceptable standards for such audits. The Department also intends to collect information from proposed auditors relating to their qualifications to conduct GMP audits and making a list of qualified third-party auditors available on the Department’s website. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Comments were received requesting that license and application fees be lowered for cannabinoid hemp processors. A commenter stated that under the proposed regulation, processors who have smaller business operations would pay license fees appropriate for large-scale processors and recommended that license fees be determined by the size of a business.

Additionally, commenters suggested creating parity between the extracting and manufacturing-only processor license fees, asserting that distinctions between the license types does not justify an increased fee for those processors that are extracting hemp. Some commenters advocated for making the application fees refundable instead of non-refundable. Alternatively, some commenters claimed that the processor license and application fees were insufficient when compared to the licensing fees for registered organizations in the medical marijuana program.

**RESPONSE:** The regulation has been amended to lower the license fees for cannabinoid hemp processors to \$3,500 for extracting and manufacturing and \$1,000 for manufacturing only. The Department intends to reevaluate the application and license fees on a recurring basis to determine appropriateness in relation to the Program’s administrative and oversight responsibilities. The processor application fee is non-refundable because it requires significant Department review regardless of whether a license is awarded. However, license fees are refundable if an applicant is not selected for licensure as a cannabinoid hemp processor.

**COMMENT:** Comments were received regarding the Department’s interpretation of “sufficient” evidence to serve as proof of an applicant’s product liability insurance and whether such insurance is readily available in the marketplace.

**RESPONSE:** The Department intends to issue guidance on the satisfactory levels of product liability insurance for cannabinoid hemp processors during the application process and the types of evidence of such insurance that will be acceptable to the Department. The Department is monitoring the availability of product liability insurance in the marketplace and may provide future rulemaking if necessary, to address the matter. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Commenters requested clarification as to whether an individual who applies for, and is subsequently granted a processor license, by the Department, is permitted to solely use sources identified in the initial application; or could such individual add additional sources of hemp or hemp extract throughout the duration of a license period.

**RESPONSE:** The Department will allow cannabinoid hemp processors to add additional sources of hemp or hemp extract throughout the license period, provided however, that each source of hemp or hemp extract meets the requirements of the regulation. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** A commenter asked why the cannabinoid hemp processor and retailer application requirements were less detailed in comparison to requirements for registered organizations in the State’s Medical Marijuana Program. Additionally, the commenter sought information regarding the functional difference between hemp and medical marijuana products.

**RESPONSE:** In accordance with the PHL, medical marijuana and cannabinoid hemp are subject to different regulatory frameworks and State programs. The comments relating to medical marijuana and registered organizations are beyond the scope of the proposed rulemaking. No changes were necessary in response to these comments.

**COMMENT:** Commenters requested the creation of a new license type for “Cannabinoid Hemp Farm Processors” which would allow farmers to create cannabinoid hemp products through infusion without being subject to some or all of the requirements of licensed cannabinoid processors. Commenters suggested the license be modeled after the New York State Department of Agriculture & Markets “home processor” exemption.

**RESPONSE:** The Department will take these comments under advisement and coordinate with the Hemp Workgroup, established pursuant to PHL § 3398-r, to explore creating a new license type through subsequent rulemaking. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Comments were received suggesting the removal of the cannabinoid hemp retail license since a license is not required to sell other food or dietary supplement products.

**RESPONSE:** PHL § 3398-c specifically requires retailers in New York State to obtain a license from the Department to sell cannabinoid hemp products. No changes were made to the proposed regulation as a result of these comments.

**COMMENTS:** Comments were received asking how the Department will enforce regulatory requirements for internet-based cannabinoid hemp retailers.

**RESPONSE:** These comments are outside the scope of the proposed regulation. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Comments were received requesting that the retail application requirements be modified to require the name of the distributor or packer, not the place of origin, in instances where such information is not available to the retailer. Additionally, commenters sought information relating to frequency by which the Department intends to request product source information.

**RESPONSE:** The Department has revised the regulation to incorporate the option of listing the distributor or packer as the source for cannabinoid hemp products if applicable. The Department

intends to request product source information annually as a condition of licensure and when appropriate to enforce the regulation.

**COMMENT:** Commenters suggested removing the requirement that cannabinoid hemp retailers provide the type of cannabinoid hemp products they intend to sell on the retailer application. Commenters also asked whether it would be permissible to add additional products after application has been submitted.

**RESPONSE:** To ensure that unauthorized products are not offered for sale, it is necessary for the Department to collect information on the type of cannabinoid hemp products a retailer intends to sell. The Department will allow cannabinoid hemp retailers to add additional types of cannabinoid hemp products throughout the license period, provided each type(s) of cannabinoid hemp product(s) meets the requirements of the regulation. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Comments were received requesting a reduction of the fee for a cannabinoid hemp retailer license. Commenters asserted that requiring a separate retailer license for each location selling cannabinoid hemp products does not account for retailers who may only be operating on a limited basis, such as at farmers markets or festivals.

**RESPONSE:** The retail license fee was determined after evaluating the Cannabinoid Hemp Program's administrative requirements for monitoring compliance and enforcement. The Department intends to reevaluate the cost of the retail license fee on a reoccurring basis to determine its appropriateness. PHL § 3398-t gives the Department the authority to create "special-use permits." The Department may exercise such authority to create a temporary

cannabinoid hemp retail permit to account for sales of cannabinoid hemp products on a limited basis. No revisions to the regulation are necessary to address these comments.

**COMMENT:** Comments were received regarding the Department’s interpretation of “parties with a controlling interest” as used in subdivision (b) of section 1005.4, and to what extent this information needs to be disclosed in the application.

**RESPONSE:** As part of the application process, applicants are required to provide ownership information to the Department. To the extent applicants have specific questions about disclosures in their application, they should reach out to the Department directly. No changes were made to the regulation as a result of these comments.

**COMMENT:** Commenters sought clarification of the provision in section 1005.4 prohibiting applicants from reapplying for six months after being denied a license.

**RESPONSE:** The requirement in subdivision (d) of section 1005.4 is intended to prevent an applicant who the Department previously denied licensure, from reapplying within six months of such denial, thereby circumventing the Department’s determination. The inclusion of the term “substantially the same” is intended for events or circumstances involving applicants that had been previously denied licensure by the Department and that apply for a license under a different business entity. To the extent additional clarification is needed, the Department may issue guidance. No changes were made to the regulation as a result of these comments.

**COMMENT:** A commenter asked what consequences will be applied in the event of a failed GMP audit.



**RESPONSE:** The Department will be issuing guidance addressing third-party GMP audits which will include information about failed audits. No changes to the proposed regulation have been made as a result of this comment.

**COMMENTS:** Commenters recommended that the Department refrain from using an applicant’s criminal history related to growing or selling marijuana as a factor in evaluating applications.

**RESPONSE:** In accordance with Article 23-A of the Correction law, the Department may only take a prior conviction into consideration when there is a “direct relationship between one or more of the previous criminal offenses and the specific license or employment sought or held by the individual.” The intent of the regulation is not to preclude applicants who were convicted of a low-level marijuana possession arrest from obtaining a license.

**COMMENTS:** Commenters recommended that the regulation define the criteria for evaluating an applicant’s “good moral character.”

**RESPONSE:** Public Health Law § 3398-g(1) sets forth the selection criteria requirements for a license and requires applicants to be of good moral character. Some of the factors the Department will consider related to “good moral character” include, but are not limited to, prior bankruptcy, criminal background, and previous license suspensions. No changes to the proposed regulation have been made as a result of these comments.

**COMMENT:** A commenter requested additional information on what constitutes a “reasonable documented effort” to extend an applicant’s six-month pre-approved period for demonstrating GMP compliance.

**RESPONSE:** The proposed regulation builds in flexibility to allow the Department to extend the period for an applicant to furnish required documents for final licensure. These matters will be determined on a case by case basis, taking into consideration the relevant facts and circumstances of an applicant's situation. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Comments were received regarding the potential penalty for a licensee who changes majority ownership or controlling interest without prior approval from the Department.

**RESPONSE:** PHL § 3398-j(3) states “a license shall become void by a change in ownership, substantial corporate change or change of location without prior written approval of the commissioner.” No changes to the proposed regulation have been made as a result of these comments.

**COMMENT:** Comments were received regarding section 1005.6(d) seeking more information about acts or omissions that constitute a violation of regulation, and whether the Department will levy a monetary fine for all violations.

**RESPONSE:** PHL § 3398-q authorizes the Department to issue penalties for the failure to comply with the statute and regulations. Violations of the statute and regulations will depend on the facts and circumstances of each case. Nonetheless, PHL § 3398-q does not mandate each violation be associated with a civil penalty. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Comments were received suggesting the restriction of hemp extraction to require that products sold in New York State may only be extracted using carbon dioxide and ethanol.

Additionally, several commenters sought information concerning the extraction methods the Department anticipates allowing, specifically whether “infusion” of hemp into a carrier oil such as olive oil will be permitted.

**RESPONSE:** The Department intends to provide guidance on cannabinoid hemp extraction methods. The Department has refrained from including a list of acceptable extraction methods in regulation in contemplation of review and approval of new extraction methods and techniques. No changes to the proposed regulation have been made as a result of these comments.

**COMMENT:** Comments were received requesting that the regulations conform cannabinoid hemp processor record keeping requirements to the federal standards governing GMP.

Additionally, one commenter asked whether only  $\Delta 9$ -Tetrahydrocannabinol was required to be tracked. Further, the commenter asked why the proposed regulation omits references to THCA. Additional comments were received on how cannabinoid hemp and hemp extract sourced out-of-state or internationally will be tracked and for products grown out of state.

**RESPONSE:** The proposed regulation requires cannabinoid hemp processors to follow federal GMP under Title 21 of the Code of Federal Regulations (CFR) Parts 111 or 117, including any provisions pertaining to record keeping. Any additional requirements for record keeping are consistent with the Department’s authority pursuant to PHL § 3398-1. The definition of total  $\Delta 9$ -Tetrahydrocannabinol in the proposed regulation already includes the measurement of THCA. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Commenters requested further detail on what it means to “test a statistically significant number of samples” as required by section 1005.7(a)(7) of the proposed regulation.

Further, commenters requested additional information on third-party testing laboratories and whether laboratories located out-of-state could perform such testing.

**RESPONSE:** The Department anticipates issuing further guidance relating to cannabinoid hemp testing sample size. The proposed regulation allows cannabinoid hemp testing laboratories located outside of New York to perform the necessary testing services for licensees, provided such laboratories meet the minimum requirements established in section 1005.10. Additionally, the proposed regulation allows testing laboratories approved to test medical marijuana products in New York State test cannabinoid hemp products.

**COMMENT:** A commenter asked why cannabinoid hemp licensees were not required to have a seed-to-sale tracking system.

**RESPONSE:** The proposed regulation adequately safeguards the proportionate risks posed by hemp extract and cannabinoid hemp. Additionally, unlike medical marijuana and adult-use cannabis markets, cannabinoid hemp products can enter interstate commerce and it would be impractical to impose a state level seed-to-sale requirement on an industry not limited to intrastate. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Several commenters suggested increasing the intermediate hemp extract THC cap of three percent (3%) to five percent (5%) or removing the cap altogether. Commenters stated that while three percent (3%) THC will capture most extract products, it will not allow processors to account for all possible scenarios. Commenters stated that if the hemp was grown under the legal limit of 0.3% THC and final products contain no more than 0.3% THC, then the intermediate hemp extract THC content should not matter. Further, commenters recommended

removing the provision that restricts sales of intermediate hemp extract to entities located outside of New York State.

**RESPONSE:** The Department will take these comments under advisement and consult with the Hemp Workgroup to determine whether additional rulemaking is necessary. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** One commenter asked whether sales of hemp extract would be taxed comparable to medical marijuana, considering hemp extract may have more than the 0.3% THC typically associated with hemp.

**RESPONSE:** Medical marijuana and cannabinoid hemp are regulated under different state programs in accordance with applicable provisions of the PHL and Tax Law. Comments relating to medical marijuana are beyond the scope of the proposed regulation. No changes were necessary in response this comment.

**COMMENT:** A commenter asked whether the regulation's requirements for cannabinoid hemp processors will apply to the processing of hemp for industrial purposes, such as textile production.

**RESPONSE:** The proposed regulation only governs cannabinoid hemp products used or intended to be used for human consumption, as defined in PHL § 3398(3). Accordingly, processors of industrial products derived from hemp are outside the scope of the proposed regulation. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Comments were received suggesting the adverse reporting requirements be amended to better conform with 21 CFR Part 111. Commenters also suggested removing the requirement that licensees notify the Department within 24 hours of learning of a serious adverse event.

**RESPONSE:** The proposed regulations incorporate provisions requiring cannabinoid hemp processors to implement and comply with requirements of 21 CFR Parts 111 and 117 depending on the finished product type, reflecting the statutory requirement in PHL § 3398-n. The requirement in the proposed regulation for cannabinoid hemp processors to report serious adverse events to the Department serves to assist the Department in monitoring serious adverse events and to protect public health and safety. No changes to the proposed regulation have been made as a result of these comments.

**COMMENT:** Comments were received inquiring how the State plans to enforce the requirement that all cannabinoid hemp products sold in New York State were manufactured using GMP. Additionally, commenters inquired as to whether the regulations will apply to out-of-state products.

**RESPONSE:** PHL § 3398-n requires all cannabinoid hemp and hemp extract to be extracted and manufactured in accordance with GMP pursuant to 21 CFR Parts 111 or 117. Accordingly, cannabinoid hemp products produced out-of-state and sold in New York State must meet the requirements of the statute and regulation. Out-of-state manufacturers and distributors of cannabinoid hemp products must adhere to the requirements of the program, to the extent they intend to sell products in New York State. No changes to the proposed regulation have been made as a result of these comments.

**COMMENT:** Commenters suggested removing the Department’s ability to impose a  $\Delta$ 9-Tetrahydrocannabinol limit on cannabinoid hemp products. Commenters stated that the limit selected by the Department could have a significant impact on the hemp marketplace and require the reformulation of otherwise legal cannabinoid hemp products. Further, commenters claimed that any action taken by the Department to impose a  $\Delta$ 9-Tetrahydrocannabinol limit, should allow for a notice and a public comment period. Alternatively, one commenter stated that the 0.3%  $\Delta$ 9-Tetrahydrocannabinol limit in cannabinoid hemp products is an insufficient safeguard against products that could be potentially intoxicating and recommended the Department lower the allowed limit of  $\Delta$ 9-Tetrahydrocannabinol in cannabinoid hemp products to 0.1%.

**RESPONSE:** In response to commenters’ concerns, the revised regulation is modified to clarify that any per milligram  $\Delta$ 9-Tetrahydrocannabinol limits on cannabinoid hemp products would be established through future rulemaking, and therefore subject to public comment.

**COMMENT:** Some commenters suggested increasing the allowable concentration of  $\Delta$ 9-Tetrahydrocannabinol in hemp from 0.3% to 1%, to allow for more robust genetics and varieties to be grown by farmers.

**RESPONSE:** PHL § 3398(5) defines “hemp” as containing a  $\Delta$ 9-Tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis. Any change to the level of  $\Delta$ 9-Tetrahydrocannabinol allowed in hemp would require a statutory amendment. No changes to the proposed regulation have been made as a result of these comments.

**COMMENT:** A commenter suggested removing the prohibition on using alcohol in cannabinoid hemp products.

**RESPONSE:** The Department will take this comment under advisement for future rulemaking, contingent on changes to federal rules regarding cannabinoids and alcohol. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** A commenter suggested incorporating a reference to the federal “Preventing Online Sales of E-Cigarettes to Children’s Act” in § 1005.8(d) of the regulation to make it clear this Act applies to the sale of inhalable cannabinoid hemp products.

**RESPONSE:** The Department intends to issue guidance if further clarification is necessary for inhalable cannabinoid hemp products and whether such products fall under the referenced Federal Act. No changes to the proposed regulation have been made as a result of this comment.

**COMMENT:** Numerous comments were received regarding the prohibition on whole flower hemp as an allowable form of a cannabinoid hemp product. Many commenters recommended the proposed regulation be amended to allow for the manufacture and sale of cannabinoid hemp flower, claiming that this product form is more cost effective and efficacious than other cannabinoid hemp product forms. Commenters also discussed the benefits of cannabinoid hemp flower products, stating that they are analogous to other cannabinoid hemp products but provide more immediately relief for mitigating certain mental or physical health issues. Commenters also suggested a prohibition on whole flower would have a negative consequence of indirectly incentivizing individuals to find alternatives in the illicit cannabinoid market without any of the benefits of being part of a regulatory framework. Comments were also received from farmers who indicated that their businesses would be negatively impacted by the prohibition on whole flower. Commenters also stated there were inconsistencies in the state’s position to legalize adult use cannabis, which would contain high levels of THC, but ban hemp flower which does



not contain high levels of THC. Further, commenters questioned the Department's decision to allow cannabinoid hemp to be vaporized while banning whole flower products, given uncertainties over the health impacts of vaporization. Finally, commenters suggested that excluding whole flower hemp is inconsistent with the federal rescheduling of hemp in the Controlled Substances Act pursuant to the 2018 federal Farm Bill.

**RESPONSE:** PHL § 3398-a(7) provides the Commissioner with broad authority to determine the forms and types of cannabinoid hemp products which may be offered for retail sale to consumers in New York State. It is the mission of the Department to protect, improve and promote the health, productivity and wellbeing of all New Yorkers, and the commitment to a smoke-free society is consistent with that mission. The regulation has been amended to clarify that flower products are permitted. However, cannabinoid hemp products clearly labeled or advertised for the purposes of smoking, or in the form of a cigarette, cigar, or pre-roll, or packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes, are prohibited. Comments about the potential medicinal benefits attributed to cannabinoid hemp products are outside the scope of the proposed rulemaking.

**COMMENT:** Numerous comments were received suggesting the prohibition on transdermal patches should be removed. Commenters expressed that transdermal patches offer an effective and safe delivery system for cannabinoid hemp products by providing a consistent dose of CBD and other cannabinoids.

**RESPONSE:** The Department revised the regulation to permit the sale of transdermal patch cannabinoid hemp products.

**COMMENT:** Commenters recommended the prohibition on cannabinoid hemp inhalers be removed. Commenters stated that inhalers have been used for years as a common drug administration device and purported that inhalers offer many of the benefits of vaping with a more precise metered dose.

**RESPONSE:** At this time, this product administration method does not appear to be widely utilized and further research is necessary to adequately examine the risks and benefits of this delivery mechanism. The Department will take these recommendations under advisement for future rulemaking and will consult with the Hemp Workgroup. No changes to the regulation were made as a result of these comments.

**COMMENT:** Commenters recommended removing the prohibition on suppositories as a product form for cannabinoid hemp products. Commenters stated suppositories are particularly beneficial for women health issue.

**RESPONSE:** The Department has revised the regulation to allow for the use and sale of cannabinoid hemp suppository products, provided such products are in compliance with additional requirements of the proposed regulation.

**COMMENT:** Numerous comments were received concerning the proposed regulation's treatment of cosmetic cannabinoid hemp products. Some commenters assumed the State is prohibiting cosmetic products, while others requested clarification as to whether topical products must adhere to the same requirements as other cannabinoid hemp products.

**RESPONSE:** The regulation excludes products that meet the FDA definition of a "cosmetic" from being regulated as cannabinoid hemp products. The regulation does not prohibit these cosmetic products containing cannabinoids from being sold. Cosmetic products containing

cannabinoids are not ingested or inhaled, and the risk to the public health and safety risks of consumers is minimal. However, topically applied products containing cannabinoids that do not meet the definition of a cosmetic fall within the definition of cannabinoid hemp set forth in Article 33-B of the PHL and are therefore subject to the regulation. The Department intends to issue guidance to further clarify what constitutes a cosmetic for purposes of the regulation. The revised rulemaking amends several provisions to account for differences in methods of administering cannabinoid hemp products that are consumed orally versus products applied topically.

**COMMENT:** Commenters suggested that the Department’s authority to prohibit additional cannabinoid hemp product forms without future rulemaking could result in significant investment concerns for cannabinoid hemp processors and retailers.

**RESPONSE:** PHL § 3398-a(7) provides the Commissioner broad authority to determine the form and types of cannabinoid hemp products which may be manufactured and offered for retail sale to consumers in New York State. It is imperative for the Department to be able to quickly and proactively respond to potential threats to public health and safety. No changes to the regulation were made as a result of these comments.

**COMMENT:** Comments were received suggesting the accuracy of cannabinoid labeling be amended from a 10% margin of error to a 20% margin of error, to parallel requirements for similar products set by the FDA.

**RESPONSE:** The Department has revised the regulation to allow for a 20% margin of error between the concentration of cannabinoids on a cannabinoid hemp product’s label and the third-party laboratory test results for such product.

**COMMENT:** Commenters proposed allowing synthetic and botanically derived terpenes to be added to inhalable cannabinoid hemp products in addition to hemp derived terpenes.

Commenters stated that these forms of terpenes are molecularly equivalent to terpenes derived from hemp and that there is no chemical difference from a natural source in comparison to a synthetic source. Commenters suggested the Department require manufacturers to label synthetic and non-hemp-derived terpenes on product labels to inform consumers.

**RESPONSE:** Due to a lack of available scientific data on the safety of inhaling vapor products, the regulation purposefully limits the excipients that can be added to such products. The Department plans to consult with the Hemp Workgroup on this topic and will take these comments under advisement for future rulemaking. No changes to the regulation were made as a result of these comments.

**COMMENT:** Some commenters stated the 25 milligram (mg) limitation on cannabinoid hemp products sold as food or beverages is too low, while others suggested removing the provision altogether as there is no scientific consensus on appropriate dosing levels for cannabinoids. Conversely, some commenters expressed concerns that the levels of cannabinoids are set too high and could result in harmful health consequences and disincentivize the development of new cannabinoid-containing prescription medicines. Commenters requested clarification as to whether the 25 mg “per product” cap applies to each multi-unit pack or each individual serving within a product. Comments were also received inquiring whether the 25 mg cap only pertains to marketed cannabinoids or, rather, to total cannabinoids in the product. Commenters also suggested an increased threshold be set for dietary supplement products above the 3,000 mg limit, to allow for larger multi-serving products and to set a per mg threshold for those products

per serving. In addition, commenters requested more information on how the Department settled on the cannabinoid content limits set in the proposed regulation.

**RESPONSE:** The proposed regulation was amended to clarify that an individually packaged food or beverage product may contain up to 25 mg of cannabinoids. The proposed regulation was also amended to clarify that the 3,000 mg limit on total cannabinoids per product for supplements is limited to no more than 75 mg per individual serving.

The 25 mg total cannabinoid limit was determined after analyzing available data on the safety profile of cannabinoid products. Particularly, the Department reviewed the analysis conducted by the United Kingdom's Food Standard Agency (FSA), which recommended healthy adults take no more than 70 mg of CBD per day. The 25 mg limit for food and beverage products will allow consumers to have multiple cannabinoid hemp products and remain in the approximate range recommended by the FSA. The proposed regulatory limit of no more than 3,000 mg of total cannabinoids per cannabinoid hemp product sold as a dietary supplement was determined after analyzing common products found in the marketplace and balancing a desire to limit overly concentrated products.

**COMMENT:** Comments were received suggesting the Department allow additional categories of cannabinoid hemp food products. Commenters suggested removing or modifying the requirements that products be shelf-stable, not potentially hazardous food, and allowing cannabinoids to be added to food products at the point of sale. Commenters claimed requiring products to be shelf-stable is not necessary to ensure the integrity, quality, or safety of the product. Alternatively, several commenters stated the Department should prohibit all cannabinoid food products, in conformance with the FDA.

**RESPONSE:** While the FDA currently prohibits the addition of CBD to food and beverage products, the availability of these products has proliferated because of the 2018 Farm Bill. New York State consumers currently have access to a plethora of cannabinoid hemp food products, which are manufactured without a clear regulatory framework establishing the allowable purpose, manner, and form of such products. As such, the regulations address cannabinoid hemp food products and regulate such products in a manner that protects the health and safety of New Yorkers. The Department will consult with the Hemp Workgroup and take these comments under advisement for future rulemaking. No changes to the regulation were made as a result of these comments.

**COMMENT:** Comments were received suggesting that section 1005.8(10)(c) of the proposed regulation be modified to make clear that capsules, tablets and other similar product forms do not require a measuring device.

**RESPONSE:** The Department has revised the regulation to address these comments.

**COMMENT:** Comments were received requesting that vaporization devices not be limited to “closed looped systems” and seeking clarification on what constitutes an inter vaporization heating material. One commenter sought clarification of the term “medical compounds” as described in section 1005.8 (10)(d)(iii). Commenters also suggested removing the requirement that excipients in cannabinoid hemp vaporization products be pharmaceutical grade and recommending that the Department establish an appeal process for licensees to use other excipients. Commenters also stated that requiring a Department approved symbol on all vaporization products manufactured after June 2021, would impose significant compliance challenges, due to considerable time to design, print, and apply the symbol to products.

**RESPONSE:** The provisions relating to cannabinoid hemp inhalable products in the proposed regulation adopt best practices from the cannabis industry and are intended to safeguard the health of consumers in New York State. The Department intends to provide further guidance for cannabinoid hemp inhalable products, if necessary. The Department revised the regulation to extend the date in which cannabinoid hemp inhalable products will need a Department approved symbol to January 1, 2022.

**COMMENT:** Several commenters noted that the packaging and labeling requirements would create specific requirements unique to New York State, making it difficult to do business in multiple states. Commenters urged the Department to consider other states' requirements for cannabinoid hemp product.

**RESPONSE:** While the Department appreciates the concerns of national manufacturers of cannabinoid hemp products, the requirements in the regulation are necessary to protect the public health and safety of New York consumers. The proposed regulation incorporates by reference several provisions of the federal regulatory framework for food and dietary supplements including, GMP and nutritional and supplement labeling. To the extent any provision conflicts with the existing federal regulations for food or dietary supplements, the Department emphasizes that the federal government has not expressly allowed the addition of cannabinoids to these product types. Whenever possible, the Department will coordinate with the federal government and other state regulators to harmonize cannabinoid hemp product requirements across applicable jurisdictions. No changes to the regulation were made as a result of these comments.

**COMMENT:** Multiple commenters suggested removing the 8-point font requirement for warnings on cannabinoid hemp products. Commenters noted that no other state, nor the FDA,

mandates such requirement and it would create issues for smaller products with limited packaging and labeling space. Multiple commenters suggested that additional warnings could be obtained from the certificate of analysis (COA), or from the manufacturer's website.

Additionally, commenters of bi-lingual brands stated the size requirement was particularly impactful due to already including multiple languages on the products label.

**RESPONSE:** The Department has modified the regulatory requirement to remove the 8-point font requirement and instead require warnings to be listed in bold font and one font size larger than other information required to be on the product label.

**COMMENT:** Multiple commenters proposed removing or modifying the required warning that cannabinoid hemp products contain THC and may cause the user to fail a drug test for marijuana. Commenters requested the warning be modified to align closer to THC warnings in other states, which merely alert consumers to the presence of THC in the product without cautioning against the possibility of a failed drug test. Commenters also noted that the proposed warning could lead consumers to believe cannabinoid hemp products contain significant amounts of THC.

Alternatively, commenters suggested that the warning only apply to "full-spectrum" cannabinoid hemp products.

**RESPONSE:** Based on available data and reporting, consumers of certain cannabinoid hemp products may fail a drug test designed to test for cannabis use. Given the potential consequences of a failed drug test, it is necessary to provide consumers with this information on cannabinoid hemp product labels. Nevertheless, the Department has amended the regulation to allow the warning to be omitted in certain circumstances.



**COMMENT:** Commenters suggested the proposed regulations should require compliance with FDA nutritional labeling requirements for food and dietary supplements under Title 21 CFR Part 101, ensuring consistency with federal labeling rules.

**RESPONSE:** Where applicable, the Department has modified the proposed regulation in response to these comments.

**COMMENT:** Commenters suggested removing the requirement to list  $\Delta$ 9-Tetrahydrocannabinol concentration, CBD, and any other cannabinoids over 0.05% on the product label in the ingredient list, as these components are naturally occurring constituents that are not permitted to be listed in the ingredients list under Title 21 CFR Part 101. Additionally, commenters stated the requirement to list all cannabinoids over 0.05% poses challenge due to testing limitations for all the cannabinoids found in the plant. Likewise, the labeling of small quantities of minor cannabinoids will likely change from batch to batch, causing manufacturers to print new labels for each unique batch. Further, commenters stated many cannabinoids only exist in very small quantities which would likely not affect the consumer. Commenters also suggested the requirement seems to conflict with FDA food labeling regulations. Finally, commenters suggested that only “marketed” rather than “measurable” cannabinoids be listed on the product label, with other cannabinoid information available from the laboratory results.

**RESPONSE:** In response to these comments the Department has modified the regulation to remove the requirement that all cannabinoids over 0.05% be listed on the product label. The revised regulation only requires marketed cannabinoids, including CBD and THC, to be on the product label. To address concerns regarding the potential violation of federal labeling requirements, the regulation has been amended to allow the cannabinoid content information to be listed outside of the nutritional or supplement fact panel.

**COMMENTS:** Comments were received highlighting that the packaging and labeling requirements failed to differentiate between cannabinoid hemp products consumed orally versus product applied topically.

**RESPONSE:** The revised regulations amend several of the packaging and labeling provisions to further distinguish topically applied cannabinoid hemp products from those products which are consumed orally.

**COMMENT:** Comments were received suggesting that processors be allowed to list the distributor and/or packer on the product label instead of the manufacture. Commenters stated this would allow the last entity in the supply chain to be listed on the label and conform to current FDA labeling practices. Commenters also noted that in some circumstances the name of the manufacturer may be proprietary for brand owners using third party manufacturers.

**RESPONSE:** The regulations have been amended to allow the distributor or packer to be listed on the product label.

**COMMENT:** Comments were received asking what information needs to be on a cannabinoid hemp product label to ensure a mechanism for adverse event reporting and whether listing the manufacturer or distributors' contact information would meet this requirement.

**RESPONSE:** The Department intends to provide additional guidance on the issue of adverse event labeling requirements and will work with the Hemp Workgroup before implementing this requirement. Until such time, the listing of the manufacturer or distributors' contact information will be considered sufficient. No changes to the proposed regulation were necessary as a result of these comments.

**COMMENTS:** Commenters stated the requirement to list the country and state of origin of the hemp used in the cannabinoid hemp product on the product label was burdensome for operators sourcing hemp from multiple states and farmers. Some commenters suggested moving the requirement to the QR code or making it available on the manufacturer’s website.

**RESPONSE:** The regulation has been revised to require only the countries of origin be listed on cannabinoid hemp product labels.

**COMMENT:** Comments were received requesting that the requirement to list an expiration date on cannabinoid hemp product packaging be modified to allow for a “best buy” date if applicable, as this would conform to FDA regulations.

**RESPONSE:** The revised regulation modifies the expiration date labeling requirements to incorporate these comments.

**COMMENT:** Comments were received to modify or eliminate the QR code requirement on cannabinoid hemp product packaging. Commenters suggested allowing the use of other technology or the use of a link which will send a consumer to a website to access the QR code. Further, some commenters suggested that this requirement should not be mandated if the retailer is able to provide a paper or electronic copy of a product’s laboratory results, as some areas in New York State do not have internet access.

**RESPONSE:** The Department has modified the proposed regulation to allow for greater flexibility in linking the QR code to the manufacturer or distributor’s webpage instead of the specific product’s certificate of analysis or laboratory test results.

**COMMENT:** Commenters expressed concern with the Departments ability to add additional packaging and labeling requirements not specifically listed in the proposed regulations.

**RESPONSE:** The Department understands that changes to packaging and labeling requirements may have an impact on cannabinoid hemp processors and retailers. Any modification to these requirements will be set out in future rulemaking subject to notice and public comment. The regulation was amended to clarify that changes would be set out in future regulations.

**COMMENT:** Commenters expressed a desire for more details to be placed in the proposed regulations around what the Department considers packaging and labeling marketed to individuals under 18 years old, and under 21 years old for inhalable cannabinoid hemp products. Commenters suggested the Department better define the term “attractive” in regulation and provided examples of what should be prohibited, such as cartoons and images popularly used to advertise to children.

**RESPONSE:** The Department has incorporated additional examples in the amended regulation to make clear what the Department considers advertising to children. This includes, but is not limited to, cartoons and images popularly used to advertise to children, and imitating a candy label.

**COMMENT:** Comments were received stating the warning in section 1005.9(f)(3), which requires that cannabinoid hemp product labels to indicate that the product has not been evaluated by the FDA, should only apply to dietary supplement cannabinoid hemp products and not food products. Commenters noted that this would more closely mirror how the FDA handles warnings for food and beverages.

**RESPONSE:** Given that the FDA has not approved the addition of CBD or other cannabinoids to food and beverage products, it is important for all cannabinoid hemp products to incorporate this warning on the product label to make consumers aware. No changes were made to the regulation as a result of these comments.

**COMMENT:** Commenters suggested combining the warnings listed in section 1005.9(f) to save label space.

**RESPONSE:** The regulation does not prohibit cannabinoid hemp processors from combining the required warnings to save label space, provided each warning is adequately addressed on the product label. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** Commenters stated that some of the laboratory testing requirements and limits were overly restrictive for the testing of cannabinoid hemp products. Alternatively, other commenters were supportive of the testing requirements.

**RESPONSE:** PHL § 3398-o requires all cannabinoid hemp processors to contract with an independent commercial laboratory to test cannabinoid hemp products pursuant to regulation. The proposed regulations are in accordance with this requirement. Many of the analytes and limits set in regulation were modeled after best practices in the medical and adult-use cannabis industry. Third-party laboratory testing is an important safeguard to ensure cannabinoid hemp products are safe for consumers and accurately reflect the cannabinoid content stated on the label. No changes were made to the regulation as a response of these comments.

**COMMENT:** Commenters stated the provision authorizing the Department to declare cannabinoid hemp products adulterated and require they be destroyed because of unenumerated analytes, contaminants or pathogens, is overly broad and potentially problematic.

**RESPONSE:** The Department has modified the proposed regulation to narrow the scope of when cannabinoid hemp products are required to be destroyed because of laboratory test results.

**COMMENT:** One commenter suggested changing the term “certificate of accreditation” to “scope of accreditation,” to better match the regulatory intent and how the term is used by industry.

**RESPONSE:** The revised regulation modifies incorporates the commenter’s recommendation.

**COMMENT:** Commenters asked whether independent commercial testing laboratories were required to be able to perform testing for all of the regulated analytes, or if testing can be performed at multiple laboratories, each performing a different aspect of the necessary testing.

**RESPONSE:** The regulation has been amended to clarify that one laboratory does not need to perform all of the required testing and that laboratories may only perform testing within their scope of accreditation.

**COMMENT:** Comments were received suggesting the requirement in section 1005.10(c), that cannabinoid hemp processors maintain records of laboratory results, be removed since laboratories are already required to maintain these records.

**RESPONSE:** This requirement is necessary to ensure transparency into the cannabinoid hemp supply chain and to maintain the ability to conduct product recalls when serious adverse events occur. No changes to the regulation were made as a result of these comments.

**COMMENT:** A number of comments were received on the proposed testing limits set for various analytes. Commenters offered suggestions to align testing limits with those established in other states' cannabis or cannabinoid hemp programs. Some commenters recommended creating different contaminant limits for inhaled versus orally consumed products. Additionally, commenters also requested more details regarding the size of samples needed to test for the different analytes. In some instances, commenters suggested adding additional tests or increasing the acceptable limits to protect consumer health and safety.

**RESPONSE:** The Department made several modifications to the proposed regulations in response to these comments. Changes include modifying the residual solvent limit for several analytes to match limits set in other jurisdictions, creating a separate testing limit threshold for metals in inhalable cannabinoid hemp products, and adding new testing requirements to detect microbials.

**COMMENT:** Many comments were received expressing concern over the requirements placed on cannabinoid hemp retailers in the proposed regulations. Commenters stated the requirements will reduce the number of retailers willing to carry and sell cannabinoid hemp products. Specially, commenters stated that the requirements that retailers maintain the certificate of analysis and evidence that cannabinoid hemp products meet all of the requirements of the regulations, especially for products manufactured out-of-state, place an unnecessary burden on retailers. Commenters noted that other states have placed this requirement on retailers in their original hemp regulations and after seeing the burden it caused amended the regulations to have the state collect the appropriate information instead of the retailer. Additionally, commenters suggested adding a time limit for how long retailers would be required to maintain such records.

**RESPONSE:** PHL § 3398-1 requires each licensee to keep records as set out by the Department. The Department modified the proposed regulation to incorporate suggestions from commenters, including setting a time limit for the duration retailers are required to keep records and removing the obligation that retailers maintain certificates of authority and other evidence demonstrating that cannabinoid hemp products meet the regulatory requirements, since this information is already required to be maintained by cannabinoid hemp processors. The remaining record keeping requirements have not been amended, as they are necessary to protect the public health and safety of consumers and maintain compliance with the program.

**COMMENT:** Many comments were received suggesting the Department remove the provision indicating that the Department may require cannabinoid hemp products be kept separate and away from other products and out of the reach of children. Commenters stated this provision will cause an undue burden on businesses and send the wrong message to consumers when similar dietary supplement products do not have the same requirements. Further, commenters suggested that this requirement could make sense for age restricted items like inhalable cannabinoid hemp products or adult-use cannabis but does not make sense for other product types.

**RESPONSE:** This provision takes into account that many cannabinoid hemp products available in the marketplace look like regular food and beverage products. To avoid accidental overconsumption of cannabinoid hemp products by consumers, the Department believes this requirement is justified to create consumer awareness. The regulations have been modified to make clear that cannabinoid hemp products need to be displayed in a manner that distinguishes them from non-cannabinoid hemp products, but not necessarily separate or out of the reach of children.



**COMMENT:** One commenter asked if the requirement in section 1005.12(a)(iii), that cannabinoid hemp products not be advertised as a marijuana or medical marijuana product, will lead to further market confusion since low THC marijuana products can be identical to cannabinoid hemp products.

**RESPONSE:** The Department will take this comment under advisement and will determine whether clarification is necessary. No changes have been made to the regulation as a result of this comment.

**COMMENT:** Comments were received asking for more details about what the New York Hemp Product standards will be and what the benefits of such certification may entail. One commenter asked whether a hemp seed originating outside of New York, but grown, extracted and manufactured in New York, would be considered a New York Hemp Product.

**RESPONSE:** “New York Hemp Product” is a designation reserved for hemp grown and processed exclusively in New York State that meets or exceeds all requirements of the Program and any additional requirements set by the Department. The Department intends to work with the New York State Hemp Workgroup and other stakeholders to determine any additional criteria necessary for certification as New York Hemp Product. No changes were made to the proposed regulation as a result of these comments.

**COMMENT:** One commenter sought more detail about the security requirements for cannabinoid hemp licensees and whether security cameras and surveillance footage will be required to be maintained to match similar requirements in the State’s Medical Marijuana Program.

**RESPONSE:** Medical marijuana and cannabinoid hemp are regulated under different laws. This comment is beyond the scope of the proposed regulation and no changes were necessary regulation as result of this comment.

**COMMENT:** Commenters asked for clarification on what type of manifests or documentation would be required to accompany hemp extract in transport. Commenters also suggested that hemp extract manufactured out of state, but that contains more than 0.3%  $\Delta$ 9-Tetrahydrocannabinol, be allowed to be transported into the state to accommodate the natural increase in  $\Delta$ 9-Tetrahydrocannabinol that occurs when intermediate products are concentrated.

**RESPONSE:** While the 2018 federal Farm Bill expressly authorizes the interstate transportation of hemp and hemp products containing less than 0.3% of  $\Delta$ 9-Tetrahydrocannabinol, it does not provide any regulation for work-in-progress-hemp-extract (WHIPE) that is over 0.3%  $\Delta$ 9-Tetrahydrocannabinol. As such, the proposed regulation only permits this type of transportation intra-state to avoid potential conflict with federal law. No changes to the regulation were made as a result of these comments.

**COMMENT:** A commenter recommended amending the requirement that hemp extract be accompanied by a certificate of analysis when in transport to a laboratory for testing.

**RESPONSE:** The Department revised the regulation to clarify that hemp extract samples, when being transported to a laboratory for product testing, do not need to be accompanied by a certificate of analysis.

**COMMENT:** Commenters asked for clarification to better understand when a distributor permit is required.

**RESPONSE:** A cannabinoid hemp distributor permit is required when a business is distributing cannabinoid hemp products manufactured outside of New York State, at wholesale, to New York State licensed cannabinoid hemp retailers. The Department anticipates issuing further guidance on this issue. No changes to the regulation were made as a result of this comment.

**COMMENT:** Comments were received requesting processors located out-of-state be authorized to sell hemp and hemp extract to New York States medical marijuana registered organizations. Additionally, commenters requested cannabinoid hemp processors be allowed to sell hemp extract to licensed adult-use cannabis operators, if and when cannabis becomes legalized in New York State.

**RESPONSE:** These comments are beyond the scope of the proposed regulations and no changes were made in response to it.

**COMMENT:** A commenter suggested the provision establishing an age limit for the retail sale of inhalable cannabinoid hemp products be lowered from 21 to 18 years of age or older.

**RESPONSE:** The restriction on the sale of inhalable cannabinoid hemp products to anyone under 21 years of age is consistent with established requirements for tobacco products. No changes to the proposed regulation were made as a result of this comment.

**COMMENT:** Commenters suggested lowering the penalties for violations of the regulations, especially for first minor first-time violations. Commenters also asked whether the penalties on licensees would be weighted or if there would be a chart setting out fines for different regulatory infractions.

**RESPONSE:** The penalties and corresponding fine limits are enumerated in PHL § 3398-q. The proposed regulations are in accordance with the statute. Penalties and fines may vary based on the severity of a violation(s) and are subject to the discretion of the Department. No changes to the proposed regulation were made as a result of these comments.

**COMMENT:** One commenter suggested that the fees for permits were too low and should be increased.

**RESPONSE:** The Department will take this comment under advisement for future rulemaking. No changes to the proposed regulation were made as a result of this comment.

**COMMENT:** Some commenters stated that while they agree with the inclusion of the incorporation by reference of Title 21 CFR Parts 101, 111, and 117 in the regulation, they advocated for dietary supplements and foods derived from hemp to be subject to the same regulatory provisions as other products in these categories, and sought to minimize state-specific regulations that place a larger burden on the hemp industry to comply with the multiple sets of regulations.

**RESPONSE:** The regulation incorporates by reference several components of the federal regulatory framework for food and dietary supplements, including GMP and labeling requirements, in an attempt to leverage existing regulatory frameworks. No changes to the proposed regulation were made as a result of these comments.

**COMMENT:** Many comments were received regarding the timing of the proposed regulations and whether they would take effect immediately. Commenters requested the Department allow time for processors and retailers to come into compliance with the new regulations and/or to sell

existing inventory. Additionally, commenters suggested other timing changes to regulation related to the acceptance of applications and extending deadlines for specific provisions.

**RESPONSE:** The revised regulation includes a new section delaying the effective date of certain sections of the regulation to address these comments and allow time for licensees to come into compliance with the Program's regulatory requirements.

**COMMENT:** A comment was received seeking to clarify the status of  $\Delta 8$ -Tetrahydrocannabinol products, which are not expressly mentioned in the proposed regulation, and whether such products are prohibited.

**RESPONSE:** The regulation has been amended to prohibit the use of  $\Delta 8$ -Tetrahydrocannabinol created through isomerization in the processing of cannabinoid hemp products.

**COMMENT:** Comments were received inquiring whether a farmer could utilize a cannabinoid hemp processor for the extraction of their hemp crop with the farmer retaining the hemp extract or cannabinoid hemp product for further commercial purposes.

**RESPONSE:** The proposed regulation does not prohibit this activity. No changes were made to the proposed regulations in response for these comments.

**COMMENT:** A number of comments referenced possible changes to the regulation to accommodate future legalization of adult-use cannabis, including the participation of cannabinoid hemp processors and retailers in the future adult-use industry.

**RESPONSE:** These comments are outside the scope of the proposed rulemaking. No changes were made as a result of these comments.

**COMMENT:** Several comments were received about hemp cultivation, including the fees to grow hemp and issues with the odor.

**RESPONSE:** These comments are beyond the scope of the proposed regulation. No changes were made as a result of these comments.

**COMMENT:** A number of commenters stated the “Regulatory Flexibility Analysis for Small Businesses and Local Governments” in the regulation package did not adequately address the costs imposed on small businesses in the proposed regulation. Commenters noted the fees for licensure and GMP compliance were burdensome for small operators, particularly farmers. Similar comments were echoed with regard to the “Rural Area Flexibility Analysis.”

**RESPONSE:** The revised regulation addresses many of the cost concerns raised by commenters. The Regulatory Flexibility Analysis for Small Businesses and the Rural Area Flexibility Analysis are consistent with the revised regulation and no changes to these Analysis have been made.

**Comment:** Commenters inquired whether the proposed regulation applies to pet and animal products containing CBD or other cannabinoids.

**Response:** The regulation only governs the manufacture and sale of cannabinoid hemp products used for human consumption, not those for animal consumption. No changes have been made to the proposed regulation as a result of these comments.

**COMMENT:** Commenters asked when the Department will establish and assemble the Hemp Workgroup pursuant to PHL§ 3398-r.

**RESPONSE:** The Department anticipates the Hemp Workgroup will be assembled following the effective date of the regulation. No changes to the regulation were made as a result of these comments.