Consumable Hemp: Manufacturer Product Submission and Upload Guide

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INTRODUCTION

This guide is designed to help consumable hemp manufacturers submit and renew their registration, as well as maintain and edit their product lists pursuant to 641 IAC 156. Manufacturers are required to create and submit a product list upon the registration of their manufacturing facility, as well as maintain up-to-date certificates of analysis (COA). After submission and HHS review, products determined to be compliant will be added to the Master Product List. Retailers and Distributors will select items from the Master Product List for retail sales and distribution. Distributors and retailers are also required to maintain an accurate product list throughout the lifecycle of their registration.

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I. Required Consumable Hemp Product List Information

- 1. "Brand Name" Pursuant to 641—156.1, this field must indicate the Brand name of the product provided by the Manufacturer. Non-cannabis examples include "Toyota", "Ford," "Coca-Cola," etc. Real world examples of Consumable Hemp Brand Names may include "Charlotte's Web," "Lumi Labs," "CV Sciences," etc.
- 2. "SKU" To avoid duplicate products upon updates, registrants must provide an identifier unique to the product (SKU), as provided on the label by the manufacturer. The generally conserved format for SKU is below:



When submitting SKU information for a product, refer to an individual product container, or request this information from the Manufacturer.

3. "Product Name" - This free-text entry represents the specific Product Name as provided by the manufacturer. In the Brand Name examples of "Toyota", "Ford," "Coca-Cola," corresponding Product Names may be "Camry," "F-150," and "Coke Zero," respectively.

In the Brand Name examples of "Charlotte's Web," "Lumi Labs," "CV Sciences," corresponding Product Names may be:

- 25MG CBD Oil Capsules
- D9 THC Strain Specific Gummies
- CBD Infused Roller

Please capitalize each individual word of the Brand Name as provided in the examples and by the Manufacturer, as well as any punctuation. **4.** "**Product Form**" – The manufacturer must assign the most appropriate "Product Form" definition for the product.

Edible

- A product that contains food, or what a reasonable person would determine as having food ingredients
- Examples include, but are not limited to gummies, chocolate, hard candies, etc.

Beverage

- Liquid products must be in containers that have 12 oz or more in volume, regardless of the indicated serving size in CFR Table 2. 12 oz containers may have less <4mg THC, but not more.
- Please section VII. Liquids and Beverages Less and Greater Than
 12 oz. for detail on compliance beverage products.

Oral

- These are products that may be ingested orally, but may not be considered edibles or include specific food ingredients
- Lipid and oil-based "tincture" products are "ingestible fats and oils" and exempt from 12 oz minimum container requirements, assuming they are not in an alcohol-based matrix. Please see Table 2 for "Fats and Oils."
- Examples include, but are not limited to unflavored tinctures, unflavored capsules or tablets, unflavored water-soluble mixes, etc.

Topical

- o This is a product intended to be applied to the skin.
- Topical products are exempt from the 4 mg THC serving limit, but cannot contain > 10 mg THC per container.

 Examples include, but are limited to lotions, creams, ointment, salves, rollers, etc.

Other

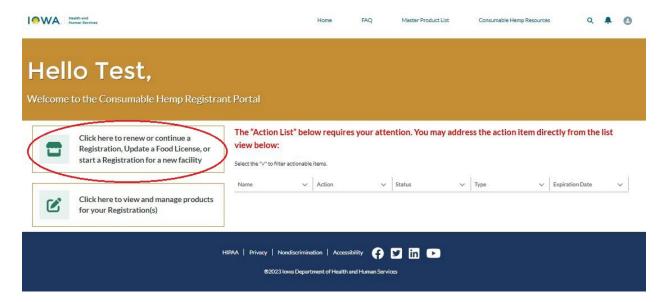
- If a product does not clearly fit into one of the above categories, please select "Other" and complete the rest of the required columns for this product.
- 5. "Total THC per Serving" Pursuant to 641—156.1, if THC is contained within, or marketed for the product by the Manufacturer the amount of THC per serving must be provided in milligrams (mg). Consumable hemp products containing more than 4 mg per serving ≥ Delta-9 THC + (0.877 × THCa) total tetrahydrocannabinol (THC) per serving will be prohibited from sale in lowa on July 1, 2024. Examples of Total THC per Serving may be "2," "2.5," or "4," etc. Enter the total THC rounded to the nearest decimal. Note: Products containing "synthetic cannabinoids," including but not limited to Delta-8, Delta-10, THC-P, HHC, THC-O etc., are prohibited in lowa.
- 6. "Total THC per Container" Pursuant to 641—156.1, a registrant must submit documentation indicating the aggregate amount of all THC per container as provided by the manufacturer. Consumable hemp products containing more than 10 mg per container ≥ Delta-9 THC + (0.877 × THCa) will be prohibited from sale in Iowa on July 1, 2024. Examples of Total THC per Container may be "2," "7.5," or "10,". Enter the total THC rounded to the nearest decimal.
- 7. "Certificate of Analysis" (COA) Pursuant to 641 IAC 156.4(1)(f), the Manufacturer must provide an accessible link or PDF document of the individual product's COA. This COA shall include:

- Information indicating the presence and concentration of THC, including delta-9 tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and any other THC for which the product is being marketed
- Information indicating the total delta-0 tetrahydrocannabinol concentration does not exceed 03. % (inclusive of any isomers, derivatives, and analogs, whether naturally occurring or synthesized)
- Information indicating the consumable hemp product is from a batch that has been tested for pesticides, residual solvents, metals, harmful pathogens, and toxicants and does not exceed limits pursuant to 641 IAC 156.3(2).
- The COA shall not be considered valid and usable for the batch of consumable hemp if its issuance date is greater than one year old.

Please review the detailed requirements for COAs <u>641 IAC 156</u> prior to submitting your product list. You may also use the <u>Certificate of Analysis</u> <u>Requirements for Consumable Hemp Products</u> guide hosted on our website. It is the responsibility of the Manufacturer to ensure each product has a corresponding, compliant COA.

II. Register your Facility

After logging in to the Consumable Hemp Registration portal, you can either create or renew an existing registration, create and update your product list, and manage your food license (if applicable). For new facilities or to renew an existing registration click the option indicated below.



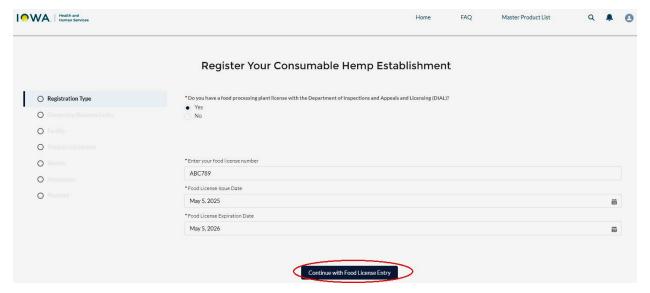
A manufacturer's product list will be created during the initial registration.
 Creating new products, updating COAs, or updating a food license can be completed anytime during the registration period. Click on "Register a New Facility" to begin.



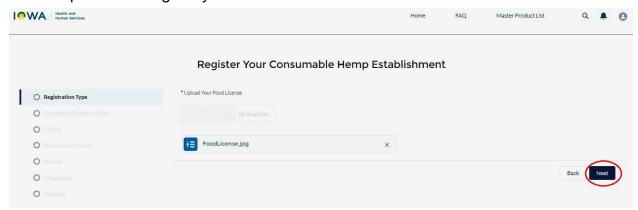
Select the appropriate registration type below.



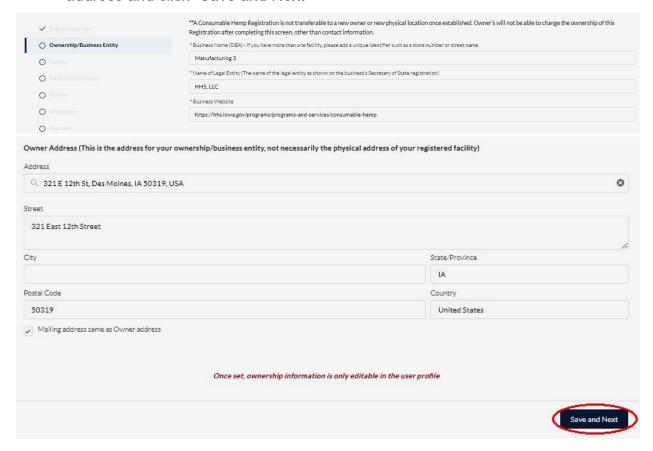
 Iowa based manufacturers will be required to upload their current food license. Enter your food license information and click "Continue with Food License Entry" to upload an image of your food license.



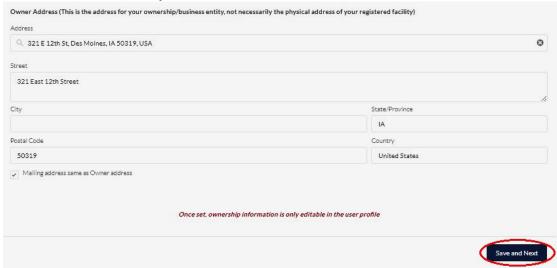
• Upload an image of your food license and click "Next"



 Complete the Ownership/Business Entity information, the name of business, legal entity, and the manufacturer's website, owner's address, and mailing address and click "Save and Next"



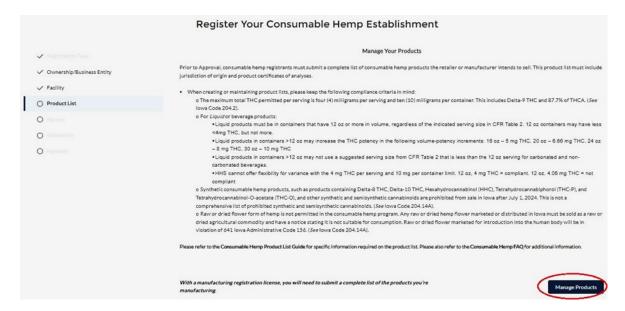
Enter the facility address and click "Save and Next"



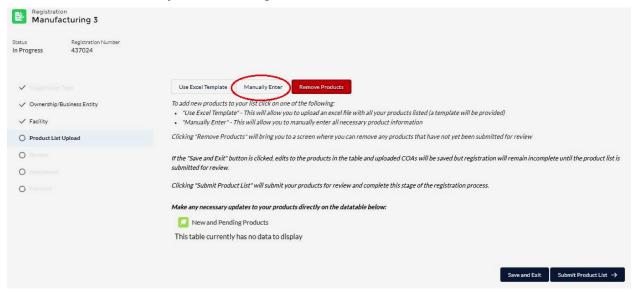
After creating your consumable hemp facility, you can proceed by submitting your product list.

III. MANUAL PRODUCT LIST ENTRY (ONE-BY-ONE)

After owner and facility information has been entered, manufacturers are required to create and submit a product list. Click on "Manage Products" to begin creating the product list.



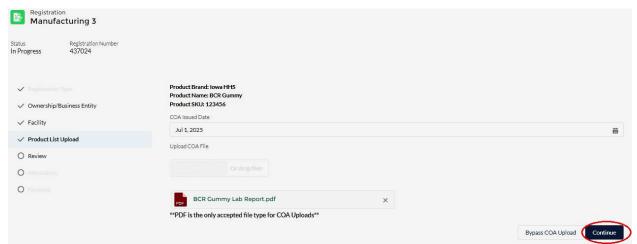
Select "Manually Enter" to begin



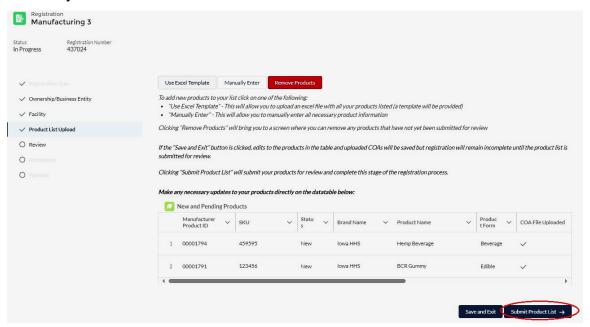
• Enter all required information; Brand Name, Product Name, SKU (must be unique), select a product form from the drop-down menu, enter Total THC per serving to the nearest decimal and Total THC per container to the nearest decimal. Provide the manufacturer website if it is different from what was entered with the ownership information. When all required information is entered, click "Save Product".



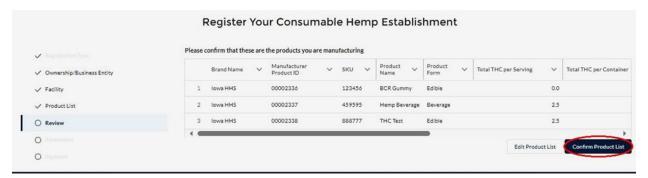
Enter the COA issue (results) date and upload the COA. Only PDFs can
be accepted for this file. COAs must have full panel test results, be issued
within the last year, include brand name, product name, serving and
container size, and batch specificity. Click on "Continue" to add more
products.



Continue entering products until your list is completed. After entering all
products and COAs, click on "Return". New products will be displayed on
the table below. Only products with corresponding COAs will be reviewed
by HHS. Click on "Submit Product List".



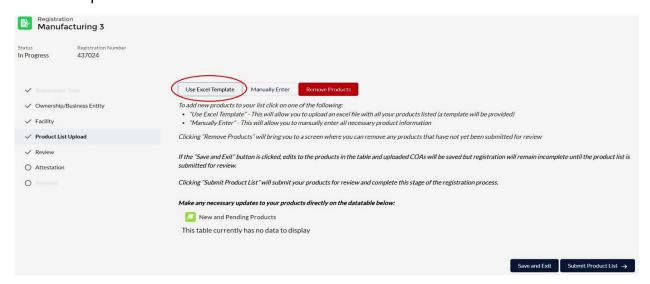
 Confirm the newly created product list. The "Active" column indicates the products have not yet been reviewed by HHS. Make any edits or click on "Confirm Product List".



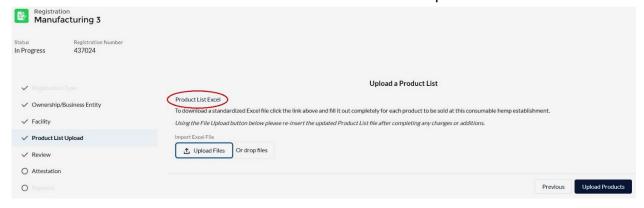
You have successfully completed the product list creation process via Manual Entry. For new or renewing Manufacturer registrations, sign and date the attestation and submit the registration fee.

IV. Product List Upload (.XLS or .CSV)

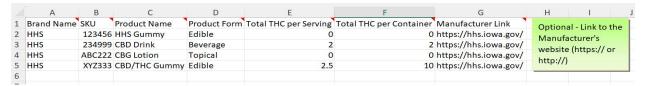
Using a .XLS or .CSV file allows manufacturers to create their product list on a spreadsheet and bulk upload all products at once into the portal. The template is preformatted by HHS and available for download in the portal. To begin, click on "Use Excel Template".



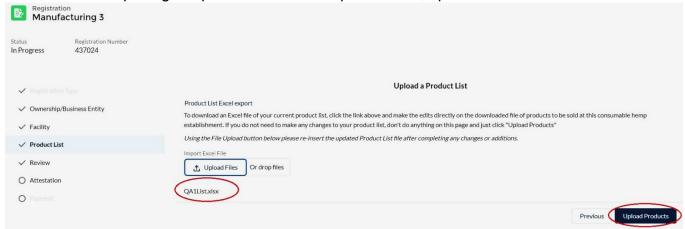
Click on the "Product List Excel" to download the template.



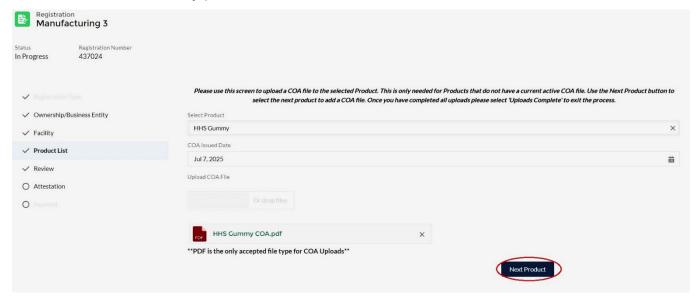
 Do not modify the first row of the template, it is pre-formatted with notes in each cell. Complete the template with each product beginning with row 2. Hovering over the cells in row 1 will display the notes for what is required in each column.



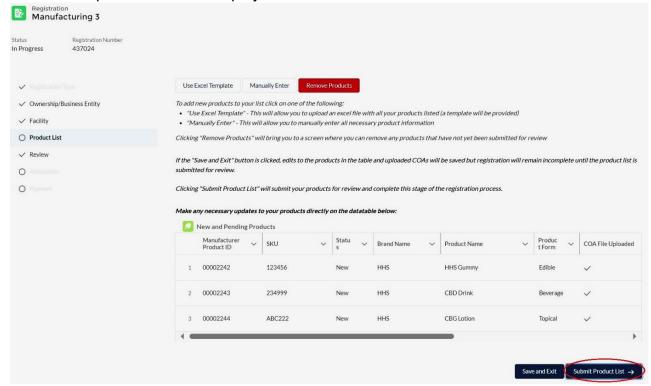
• After completing the product list on the spreadsheet, upload the file.



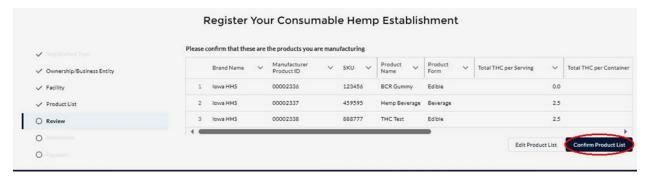
 Each product uploaded will require a COA. Upload the corresponding COA with each product along with the COA issue date (date of lab results). Click on "Next Product" until every product has a COA.



• New products will be displayed on the table below. Click on "Submit Product List"



 Product submissions can be reviewed before final submission. Edits can still be made in the table if needed, otherwise click on "Confirm Product List".

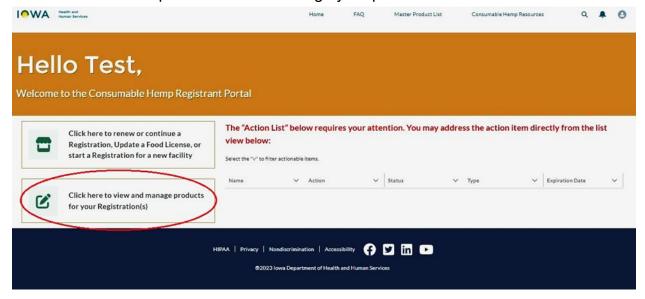


You have successfully completed the product list creation process with the spreadsheet. For new or renewing Manufacturer registrations, sign and date the attestation and submit the registration fee.

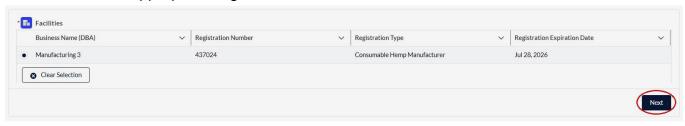
V. MANAGING AND UPDATING COAs

COAs can be updated at any time during the registration period of a manufacturer. COAs must contain compliant information and meet all requirements pursuant to (641 IAC 156.) including but not limited to brand name, product name, batch specificity, full panel test results indicating less than trace amounts of pesticides, residual solvents, metals, pathogens, cannabinoid content and potency. You may also use the Certificate of Analysis Requirements for Consumable Hemp Products guide hosted on our website. To update a COA, follow the steps below.

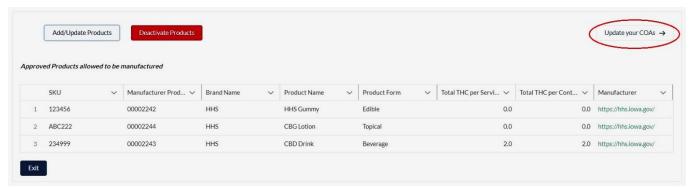
Click on the option to view and mange your products.



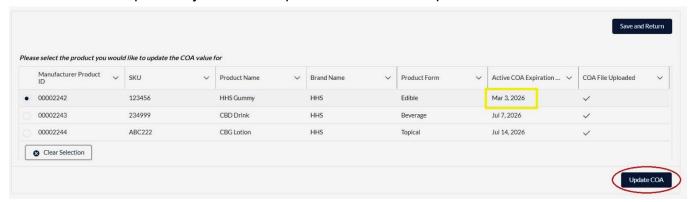
Select the appropriate registration and click "Next"



 The product list is displayed; you can add/update products, deactivate products, or update your COA. Click on "Update your COAs"



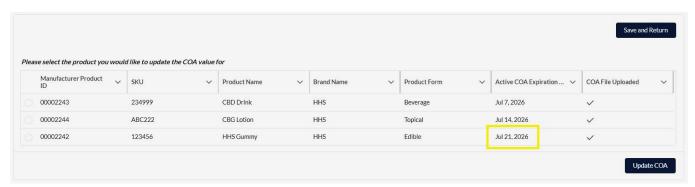
• Select the product you wish to update and click on "Update COA"



 Enter the issue (date of test results) and upload the new COA. Click "Next"



 The Active COA Expiration has now been updated. HHS will review the COA to confirm issue date and other required information. Click on "Save and Return" to exit.



VI. Prohibited Products, Compliance, and Penalties

Prohibited Product	Citation	Penalty
Inhalable Products	Iowa Code 204.14A	Serious misdemeanor, civil penalty of up to \$2,500 per violation, confiscation and disposal of noncompliant products, and/or suspension or revocation of future registrations
Products exceeding 4 mg THC per serving and/or 10 mg THC per container	lowa Code 204.2(2)(c)(2)(b)	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations
Liquids under 12 fluid ounces	Iowa Code 204.7(1)(c), 641 IAC 156.1	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations
Adulterated Products	641 IAC 156.1, 156.6(5)	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations
Synthetic Cannabinoids	Iowa Code 204.14A(3)	Serious misdemeanor, civil penalty of up to \$2,500 per violation, confiscation and disposal of noncompliant products, and/or suspension or revocation of future registrations
Products exceeding 0.3% THC	Iowa Code 204.2(2)(c)(2)(a)	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations
"Flower" or "bud" form	Iowa Code 204.14A	Serious misdemeanor, civil penalty of up to \$2,500 per violation, confiscation and disposal of non- compliant products, and/or



		suspension or revocation of future registrations
Products marketed to or intended to cure, treat, mitigate, prevent disease, or affect the structure of the human body (this includes over-the-counter medications).	641 IAC 156.4(1), 156.6(3)	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations
Bread, cake, pie, or other "cottage food" items made in a person's home kitchen or other residential space	641 IAC 156.6(1)	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations
Manufactured alcoholic beverages, meat or poultry products, or dairy products infused with hemp	641 IAC 156.5	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations. May also be subject to penalty under lowa Code 137F, 137D, 123, 189A, or 190-192
Other food not produced in a licensed food-processing plant	Iowa Code 204.7(1)	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations
Products manufactured in other countries or jurisdictions without an approved USDA hemp plan	Iowa Code 204.7(6)	Civil penalty of up to \$2,500 per violation, confiscation and disposal of non-compliant products, and/or suspension or revocation of future registrations

Submission of non-compliant product forms may be grounds for the pending and/or denial of a registration.

VII. Liquids and Beverages, Less and Greater Than 12 oz.

Statute and Administrative rule do not further define or indicate that any "liquid consumable hemp product" is exempt from the requirement for the container to be a minimum of 12 fl oz. This means that regardless of serving sizes indicated in Table 2 for a liquid consumable hemp product, the container must be 12 oz or greater to be compliant and added to a product list.

Additionally, for any liquid consumable hemp product packaged in a container >12 oz and containing greater than one serving, the incremental increase in THC potency shall not exceed the following volume-potency increments listed in Table 1:

Table 1.

Volume	Servings	THC Potency
12 oz	1	4.00 mg
16 oz	1.33	5.33 mg
20 oz	1.66	6.66 mg
24 oz	2.0	8.00 mg
30 oz	2.5	10.00 mg

Regardless of the serving size indicated in Table 2, beverage or liquid products packaged in containers >12 oz may not use a multiple of a serving size <12 oz ("juices, fruit drinks, syrups, drink mixes, etc.) as indicated by the standard 12 oz serving size for "beverages." Some examples are provided below:

Examples:

Product	Volume, THC Potency	Servings	Compliant
Beverage - Carbonated/non- carbonated	12 oz, 4 mg	1	Yes
Beverage - Carbonated/non- carbonated	16 oz, 5 mg	1-2	Yes



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Beverage - Carbonated/non- carbonated	16 oz, 10 mg	2	No, does not follow Table 1
Fruit drink	8 oz, 4 mg	1	No, container <12 oz
Fruit drink	16 oz, 8 mg	2	No, does not follow Table 1
Drink mix, syrup	4 oz, 4 mg	1	No, container <12 oz

HHS does not have authority to provide flexibility for variance from the 4 mg THC per serving or 10 mg THC per container limit. Compliant products must contain a COA that indicates less than those serving limits for a compliant volume-potency claim, or rounds down to those limits. Some examples are provided below:

Examples:

Product, Volume	Per Serving Label Claim (THC)	Per Serving COA Value (THC)	Compliant
Beverage, 10 oz	2.5 mg	2.5 mg	No, container <12 oz
Beverage, 12 oz	4 mg	3.85 mg	Yes
Beverage, 12 oz	4 mg	4.04 mg	Yes
Beverage, 12 oz	4 mg	4.06 mg	No, >4 mg THC/serving
Beverage, 16 oz	5 mg	5.13 mg	Yes
Beverage, 16 0z	5 mg	5.41 mg	No, >4 mg THC/serving

Additionally, lipid and oil-based "tincture" products are "ingestible fats and oils" and exempt from 12 oz minimum container requirements, assuming they are not in an alcohol-based matrix. Please see Table 2 for "Fats and Oils."

Conclusion

- Liquid products must be in containers that have 12 oz or more in volume, regardless of the indicated serving size in Table 2. 12 oz containers may have less <4mg THC, but not more.
- Liquid products in containers >12 oz may increase the THC potency to correlate with the volume-potency table above
- Liquid products in containers >12 oz may not use a suggested serving size from Table 2 that is less than the 12 oz serving for carbonated and non-carbonated beverages.
- HHS cannot offer flexibility for variance with the 4 mg THC per serving and 10 mg per container limit.
- Oil- or lipid-based tinctures (does not contain an alcohol matrix) are permissible in <12 oz containers and follow serving suggestions from Table 2.

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