

New York State Department of Agriculture and Markets

**CBD Processor Research Partner Application
Industrial Hemp Agricultural Research Pilot Program**

Frequently Asked Questions

Please send any questions to IndustrialHempNYS@agriculture.ny.gov.

Please be advised that:

- **The answers to the following questions are provided only as guidance. They do not bind the Department and are subject to change.**
- **In the event that an answer to a question is unclear or conflicts with the terms of the Research Partner Agreement, the terms of the Research Partner Agreement will control.**

DECEMBER 18, 2018

If I want to grow industrial hemp and also process industrial hemp, do I need to fill out two forms and pay two fees?

Yes.

When can I start doing my work?

If your application is approved, you will be sent a Research Partner Agreement that you must sign and return. Once the signed Research Partner Agreement is received by us, we will send you a dated Certificate of Authorization. That is the date you formally become a Research Partner and can begin your research. It is also the date your Annual Report is due every year.

Are there any restrictions to what I can do with CBD?

*You can **make** and **research** the use of CBD, as long as (1) it is listed in the Research Plan in your application and (2) you are in compliance with all provisions of the Research Partner Agreement.*

*What you cannot do is **sell** any item for human consumption that has CBD as an ingredient unless you meet two additional standards: (3) the item is produced under the rigorous dietary-supplement standards described in the Research Partner Agreement and (4) the item is properly labeled and packaged for sale pursuant to FDA regulations for dietary supplements. This is subject to change.*

Industrial hemp processors vs product manufacturers. If I want to use pre-manufactured CBD and add it to something else (like a topical), do I need to apply to the program as a processor?

No.

Do I need to apply to the program as a CBD processor if I want to source CBD product from out of state?

No.

Can I send my industrial hemp material to be processed out of state and returned to me in NY to sell?

Consult an attorney regarding interstate transport of industrial hemp and hemp-derived products. Products made from industrial hemp that are sold in NYS must meet NYS standards, regardless of where the product is processed or manufactured.

What is the difference between a dietary supplement and a food product?

No product for human consumption that has CBD added to it can be labeled and marketed as a food. All extracted CBD and CBD products must be manufactured pursuant to FDA dietary supplement standards and must be labeled and marketed as a dietary supplement. See the [CBD Processor Sample Research Partner Agreement](#) for references to the applicable Code of Federal Regulations.

What are “dietary-supplement standards” or “dietary supplement GMP”?

The FDA sets three levels of Good Manufacturing Practices (GMPs): one GMP standard for foods, a more rigorous GMP standard for dietary supplements, and an extremely rigorous GMP for pharmaceuticals. Products listing CBD as an ingredient must be manufactured pursuant to the dietary-supplement standards.



The dietary supplement GMPs are federal, and are described here:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=111>

This section is titled “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.” Any product for human consumption that lists CBD as an ingredient must be manufactured pursuant to these dietary-supplement standards.

How can I find out how to comply with the dietary supplement GMP?

Several companies also offer consulting services for construction of new facilities or retrofit of existing facilities to meet dietary-supplement GMP standards. Also, the FDA has many resources online describing how to comply with dietary supplement GMPs, such as this webpage:

<https://www.fda.gov/food/guidanceregulation/cgmp/ucm079496.htm>

Can I produce and sell CBD extracts?

Extracts are considered a dietary supplement. Therefore, such a product can be sold if (1) it is listed in your Research Plan and (2) it is produced in a facility meeting dietary-supplement GMP standards and (3) it is properly labeled and packaged for sale pursuant to FDA regulations for dietary supplements and (4) you are in compliance with all provisions of the Research Partner Agreement. This is subject to change.

Can I produce and sell bottled tea made with concentrated CBD extract?

The product you just described is a dietary supplement and could not be sold as a food. If this CBD tea (1) is listed in your Research Plan and (2) is produced in a facility meeting dietary-supplement GMP standards and (3) is properly labeled and packaged for sale pursuant to FDA regulations for dietary supplements, and (4) you are in compliance with all provisions of the Research Partner Agreement, then this product can be sold. This is subject to change.

Are there certain methods that I must use to extract CBD?

The initial extraction method must either use CO2 or human grade ethanol as the solvent. This is subject to change.

Can I produce and sell chocolates with CBD drizzle?

Not as a food product. However, these chocolates could be sold if they are manufactured, packaged, labeled, and marketed as a dietary supplement. If the chocolates are (1) listed in your Research Plan and (2) produced in a facility meeting dietary-supplement GMP standards and (3) properly labeled and packaged for sale pursuant to FDA regulations for dietary supplements, and (4) you are in compliance with all provisions of the Research Partner Agreement, then these chocolates can be sold. This is subject to change.

Can I make and sell a product that is a combination of ready-to-eat food with additional CBD infusions or CBD extracts, such as CBD chocolate syrup or CBD soda or CBD-infused frosting drizzled cookies?

No. Food is made under food GMP standards, which means it does not meet dietary supplement GMP standards.

Can I use an accredited/certified laboratory from out of state to test my product?

Yes.

Can I make and sell any CBD products for consumption by children?

No.

Can I make and sell a product for use in any vaping or inhalation system?

No.

Where am I allowed to sell my CBD products?

There are currently no restrictions on locations where products developed within the New York State Industrial Hemp Research Pilot Program can be sold. This is subject to change.

Can CBD products produced in NY be sold in other states?

Consult an attorney regarding other states' laws and regarding the interstate transport of industrial hemp and hemp-derived products.

Do I need any special license to sell my CBD products?

You do not need any license from the NYS Department of Agriculture & Markets to sell dietary supplements (which includes all products for human consumption with CBD as an ingredient). This is subject to change.

I currently have a retail food store license from Ag & Markets (an Article 28A license). Does this license prohibit me from selling CBD products?

No. Your 28A license only covers the sale of food. Any CBD products for human consumption are not treated as food, they are treated as dietary supplements.

Can I process hemp from a pilot program participant in another state?

Nothing in New York State law prohibits this, but you should consult an attorney regarding interstate transport of industrial hemp and hemp-derived products. The new farm bill will influence policies on interstate transportation.