

# Growing and Selling Herb Products

Patricia Kyritsi Howell, RH (AHG)

Organic Growers School Spring Conference

March 2020

[www.wildhealingherbs.com](http://www.wildhealingherbs.com)

[info@wildhealingherbs.com](mailto:info@wildhealingherbs.com)

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## Considerations for Cultivated Herbs

Annual or Perennial

Plant Parts Used: Aerial, Roots or Other

Sun or Shade Grown

Processing Herbs:

Dried or Fresh

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## Reality Check(list)

- business plan
- business entity: LLC, Corporation, sole proprietor
- banking & bookkeeping
- product development
- manufacturing
- marketing and distribution
- taxes: income & sales
- licenses, permits, etc.
- liability insurance

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## Alphabet Soup

INC – corporation

LLC – limited liability corporation

DBA – doing business as, same as sole proprietor

EIN – employer identification number

STN – sales tax number, also resale tax number

IRS – I think you know this one?

FDA – Food and Drug Administration

cGMP – Current Good Manufacturing Practice

DSHEA – Dietary Supplement Health & Education Act of 1994

AHPA – American Herbal Products Association

AHG – American Herbalists Guild

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## Your Business

Establish your business entity

- Sole proprietor/DBA
- LLC – limited liability corporation
- Inc. – corporation, C or S

Free business planning info: [www.source.org](http://www.source.org)

Also universities, chamber of commerce, etc.?

Set up your business entity on-line:

[www.nolo.com](http://www.nolo.com)

[www.legalzoom.com](http://www.legalzoom.com)

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## A few helpful sales tax facts

Wholesale: you don't pay sales tax when you buy; but obligates you to collect sales tax when you sell

Retail: the price of your product, you collect/pay the sales tax

Request a Federal EIN, then a STN or resale tax number through your Secretary of State office.

[www.wikihow.com/get-a-resale-number](http://www.wikihow.com/get-a-resale-number)

Once you obtain a resale tax number you must file monthly sales tax reports, even if you don't sell anything that month

Recent change in laws regarding on-line and out of state sales. Find out more here: <https://www.nolo.com/legal-encyclopedia/50-state-guide-internet-sales-tax-laws.html>

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### A few more tax facts

#### Allowable business deductions include

- books, magazine, newspapers
- website creation and maintenance
- tuition for conferences, trainings
- travel meals/entertainment
- lodging while doing business
- mileage (not gas)
- a portion of your phone bill
- advertising costs
- professional services (tax prep, cleaning, consultations)
- equipment used in manufacturing
- computer, hardware/software
- banking fees, credit card processing fees

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### The last tax facts...

#### Annual inventory included in tax returns

- all products
- bulk herbs
- medicine making supplies (oils, ETOH, etc.)
- shipping/packing materials

#### Bookkeeping software?

QuickBooks, etc.

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Two categories of regulations  
for manufacturing and selling herb products

**Cottage Food Laws** - Prepared in a home kitchen, requires an inspection, each state has its own regulations.

Includes home-made products include salves, certain teas, bath salts, lotions, spice blends, cosmetics, jam/jelly, baked goods, etc.

Find Cottage Laws for your state here:

[www.pickyourown.org/CottageFoodLawsByState.htm](http://www.pickyourown.org/CottageFoodLawsByState.htm)

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Licenses, permits, etc.

DSHEA

Dietary & Supplement Health & Education Act (1994)

- regulates manufacturing of herbal products
- establishes herbs as new category between foods & drugs
- Requires compliance with cGMP procedures
- no exceptions for small businesses
- exceptions for practitioners

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## Licenses, permits, etc.

cGMP Regulations – governs herbs and supplements used internally

Manufactured products such as tinctures (all types), syrups, bitters, glycerites, etc.

Regulates every aspect of production

Tracking for *everything* used in creating the product – herbs, jars, labels, oils, menstruums, etc.

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## Licenses, permits, etc.

### cGMP – Current Good Manufacturing Practices

- preparations intended for internal use
- enforced by FDA
- regulates identity, strength, quality and purity
- requires extensive record keeping
- commercial certification needed for facility
- strictly controls manufacturing procedures
- without cGMP, products are considered “adulterated”

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### The challenges of cGMP for small businesses

- originally designed to crack down on weight loss supplements with undisclosed ingredients
- no distinction between small and large manufacturers
- 3<sup>rd</sup> party testing of plant materials must be verified, microscopic and chromatography screening, DNA validation, no organoleptics (using the sense to ID)
- every ingredient and all supplies used must be tracked (where were they grown/manufactured)
- samples of every batch must be kept for years

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### Lessons Learned: Urban Moonshine

*"It's hard to be a small business  
in a heavily regulated industry."* Jovial King

- started by Jovial King as a home-based small business making tincture and bitters
- as business grew, struggled to meet FDA cGMP standards
- grew to \$2 million in annual sales
- last year, sold to Traditional Medicinals

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## Lessons Learned: Urban Moonshine

Be sure your business plans  
includes not only your vision for growth  
but also your limits.\*

\*You can change this later if needed.

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## Insurance

“serious adverse effects”

**Product Liability Insurance** protects against

- bodily injury claims
- attorney & lawsuit settlement costs

Farm Insurance?

Umbrella Policy?

Practitioner?

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## Your product line

- start small
  - 3 to 5 products maximum
- pricing
  - wholesale: double costs + labor
  - retail: double your wholesale price

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## Your product line

- herb sourcing
  - cultivated
  - foraged
  - wholesale herb suppliers
    - *But* you must have a *continuous* source of each ingredient
- other supplies
  - containers, jars, bags, labels, packing/shipping materials
  - oils, glycerin, ETOH, vinegar, etc.

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## Your product line

### Herbs sources

- Frontier
- Bulk Herb Store
- Mountain Rose Herbs
- Starwest

### Containers

- SKS Bottle
- Frontier
- BayouSome

### Packing/shipping/bags/etc

- Uline

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## Labeling

### Labels must include

- statement of identity
- net quantity of contents
- other ingredients (descending order)
- directions for use
- common name/botanical name
- proprietary blend details
- manufacturer contact info
- Supplement Facts panel (if for internal use)

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## Labeling

Book: *Herbs of Commerce*, \$99

Federal regulations require botanical names to conform to standardized names included in this publication from AHPA

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## Labeling

Teas - If your label does *not* claim to affect the human body your tea is categorized as food and regulated by Cottage Laws

Formulations - Even if you purchase individual tinctures or other preparations from other manufacturers, once you open the container and recombine them, cGMP regulations apply

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Labeling (The fun part!)

Branding

Logo

Label Design

Label source: [www.onlinelabels.com](http://www.onlinelabels.com)

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Structure/Function

If you make a claim about what your product **does** it must fall strictly under the definition of a structure/function claim.

Be prepared to supply “appropriate evidence” to substantiate your claim. Ideally randomized, placebo-controlled studies.

Premarket notification substantiating structure/function claim must be submitted to FDA.

All manufacturers of any size are required to register with FDA (via their website).

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## Structure/Function

“This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.”

Product names can be considered drug claims if it implies that it treats a health problem.

Brochures, catalogues, advertising are under the same restrictions.

Claim related violations are the most common type of FDA violation.

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Yes, it is overwhelming....

For all the details, consult the FDA cGMP for Dietary Supplements: Small Entity Compliance Guide

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SmallBusiness/default.htm>

Check out the Bionetwork class schedule:  
<https://ncbionetwork.org/>

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## Other resources

American Herbal Products Association, [www.ahpa.org/](http://www.ahpa.org/)

American Herbalists Guild,  
[www.americanherbalistsguild.com/legal-and-regulatory-faqs](http://www.americanherbalistsguild.com/legal-and-regulatory-faqs)

cGMP info for Herbalists, by Holly Hutton

<https://static1.squarespace.com/static/54f956ebe4b0a816536fe661/t/552afb8ce4b02dd28bd033f0/1428880268535/GMP+compliance.pdf>

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## To Market, To Market!

### On-line sales

- your website
- Etsy, etc.

### Retail Sales

- farmer's markets, fairs, conferences, shops

### Consultations

- recommendations with a consultation

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To Market, To Market

Other sales options

- private labeling
- bulk pricing
- consignments
- practitioners

Samples

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Getting paid

Establish your pricing policy and payment terms (and then stick to them!)

Square or PayPal credit/debit card payments go directly to your bank account

Woocommerce – Square interface for the web

Packaged websites with payment interface

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Good luck with your herbal ventures!