Growing and Selling Herb Products

Patricia Kyritsi Howell, RH (AHG)

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www.wildhealingherbs.com
info@wildhealingherbs.com

Considerations for Cultivated Herbs

Annual or Perennial

Plant Parts Used: Aerial, Roots or Other

Sun or Shade Grown

Processing Herbs:
Dried or Fresh
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

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
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
Also universities, chamber of commerce, etc.?

Set up your business entity on-line:
www.nolo.com
www.legalzoom.com

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

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

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

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.
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.orgCottageFoodLawsByState.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
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”
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

• 3rd 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

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
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.

Insurance

“serious adverse effects”

Product Liability Insurance protects against
- bodily injury claims
- attorney & lawsuit settlement costs

Farm Insurance?
Umbrella Policy?
Practitioner?
Your product line

• start small
  • 3 to 5 products maximum

• pricing
  • wholesale: double costs + labor
  • retail: double your wholesale price

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.
Your product line

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

Containers
- SKS Bottle
- Frontier
- Bayousome

Packing/shipping/bags/etc
- Uline

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)
Labeling

Book: *Herbs of Commerce*, $99

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

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
Labeling (The fun part!)

Branding

Logo

Label Design

Label source: www.onlinelabels.com

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).
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.

Yes, it is overwhelming....

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


Check out the Bionetwork class schedule:
https://ncbionetwork.org/
Other resources


American Herbalists Guild,

cGMP info for Herbalists, by Holly Hutton
https://static1.squarespace.com/static/54f956ebe4b0a816536fe661/t/552afb8ce4b02dd28bd033f0/1428880268535/GMP+compliance.pdf

To Market, To Market!

On-line sales
 - your website
 - Etsy, etc.

Retail Sales
 - farmer’s markets, fairs, conferences, shops

Consultations
 - recommendations with a consultation
To Market, To Market

Other sales options
- private labeling
- bulk pricing
- consignments
- practitioners

Samples

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
Good luck with your herbal ventures!