GMP's- Federal Oversight of Herbalists and Herbal Products

Part 1: What you make and how it is regulated.

- Teas and whole plant herbs are considered food and regulated under your State's Department of Agriculture (USDA)
- Tinctures, capsules, syrups, tablets or product that is consumed orally is considered a dietary supplement, which is a sub category of food. If claims are made on herbal products to "cure" a disease then they are then considered a drug. Although if a tinctures says "clean and detoxify" is considered a food. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm2007006.htm
- Salves, lotions and balms for soothing purposes are regulated as cosmetics. http://www.fda.gov/Cosmetics
- Liniments, bolus, sunscreen, suppositories, nasal sprays, or other products similar to these are considered a drug.

Part 2: Who is and isn't compelled to comply with GMP regulations.

I have written this to help other herbalists start to navigate the current regulations of the DSHEA (Dietary Supplement Health and Education Act). According to information on the American Herbal Guild (AHG) web site under legal and regulatory FAQ's of the DSHEA, it indicates that for anyone who opens a bottle, mixes contents, puts on their own label, or does anything that in anyways alters the original product, including clinicians, are subject to DSHEA compliance (http://www.americanherbalistsguild.com/legal-and-regulatory-faqs). There is an excellent reference article in the Journal of the American Herbalists Guild, volume 11/number 1/winter 2012 "Herbal Products GMPs 101", authored by Roy Upton, Executive Director, of the American Herbal Pharmacopoeia, he indicates that the Federal Department of Agriculture (FDA) will choose on a case-by-case basis if they will apply their authority when inspecting practitioners. In other words, the FDA when writing the DSHEA legislation chose not to exempt clinical herbalists from GMP compliance.

In a blog authored by Rosalee de la Forest in 2009, based on notes from a lecture by Roy Upton, given at a seminar at the East West School of Planetary Herbology, indicated that the FDA declared the following: *"We decline to exempt herbalist practitioners from the proposed rule. If an herbalist practitioner introduces or delivers for introduction into interstate commerce, a dietary ingredient or dietary supplement, that practitioner must use the same good manufacturing practices as other manufacturers to ensure that their clients receive dietary supplements that are not adulterated. The risks of adulteration are not eliminated just because the practitioner is an herbalist. Therefore, we decline to exempt "herbalist'' practitioners who manufacture dietary ingredients and dietary supplements. Herbalist practitioners who introduce or deliver for introduction into interstate commerce, a dietary ingredient or dietary supplement, are manufacturers who must meet CGMPs."*

According to Rosalee's blog to avoid FDA scrutiny clinical herbalists should have a direct personal consolation with the person buying their product. http://www.methowvalleyherbs.com/2009/08/fda-on-gmps-notes-on-lecture-by-roy.html . In a quote from the American Herbal Guild article authored by Roy Upton, the FDA said the following *"We believe that a one-on-one consultation by a trained practitioner many not necessitate the same types of controls we are establishing in the final rule for manufacturing activities that are on a large scale".* The article also states that the FDA will consider the exercise of their enforcement on as case-by-case basis. My take away from this information is that if the FDA wants to exercise its authority, then no one is exempt. Another argument in favor of utilizing Good Manufacturing Practices (GMP's) in your practice is that it could in limiting your potential liability, ensure quality medicine and ultimately protect your clients or consumers. If you are an herbalist who

also supports themselves making and selling herbal products to the general public then this information definitely applies to you.

There are two regulatory bodies that oversee herbal products, the United States Department of Agriculture (USDA) and the Federal Department of Agriculture (FDA). Both agencies use the same standards called "GMP's" (good manufacturing practices). If you make tinctures or teas that you sell to the public these are considered food and fall under your state's USDA, which oversees food standards. To comply will need to have a domestic kitchen license or work in a commercially certified kitchen. The license in my state costs $325 a year for a commercial certified kitchen or $300 for a domestic kitchen license, although this can vary from state to state. It is important to review your State's standards, and then contact your State's Agriculture Department to set up an inspection. For a domestic kitchen license you need to have the following: separation from other living areas, no animals allowed in the domicile and utilization of a three-compartment rinse (www.healthdepartment.org/.../3%20compartment%20**sink**.pdf*).* If you are using a commercial kitchen the inspector will still need to meet with you on site and require you to have separate storage space. The disadvantage of using a commercial kitchen is that you often have kitchen rental fees in addition to the costs of the license. In working with an inspector it is important to recognize that they are very rule bound and it is important to not ask them to bend the rules. Once the inspection is complete you will receive a report with a list of items to be addressed within a specific timeframe. Once the inspector is satisfied that you have completed the list and you have paid the license fees, you are good to go at least until the following year when it starts all over again.

Good Manufacturing Practices (GMP's): The following is my attempt to walk you through the process of complying with GMP's and/or establishing best practices. It is important to recognize that this is just a beginning template and continuing to educate yourself on these regulations is imperative. As a starting point you need to have a policy and procedures manual (Standard Operating Procedures) that outlines the steps taken through the entire manufacturing process. You probably already have a process in place that you use so write it down and this becomes the backbone of your SOP manual. It starts when you receive herbs or grow herbs that you use in your practice. You need to ensure that the herb you are using is what it says it is. I have a notebook set up that has samples of herbs, including their common and Latin names. I can use this notebook to compare to the herbs I receive for a visual examination I then smell and taste the herb. This process is called a visual and organoleptic assessment. If something has been wildcrafted by you, then saving a plant pressing is helpful for substantiation. I document this verification in a form I developed that lists the lot number of the herb or if it is an herb I have grown I assign a lot number. This is necessary so you can track the herb through the entire manufacturing process and if there is a recall or an issue you are able to go back through your records and pull product.

Date received	Supplier	Product description	Method of Verification	Lot#
2/17/15	Mayway	Ziziphus seed	Organoleptic	MC10456

I leave the herbs in their original containers where they are clearly marked with the lot and date from the supplier. I have a recipe book (Master Manufacturing Manual) that specifies the name and quantity of all ingredients in each product that I make for sell to the general public. In addition to the MMM I also have written procedure/instruction that include how to make products, how to establish batch numbers, steps on documentation of ingredients and sanitation procedures. The next step in

the process is when I make products, whether they are custom formulas or for sell to the public, I establish a batch production record (BPR) that includes the date of manufacture, the batch number, who the product is intended for, a list of herbs used, the supplier name and lot numbers of each herb.

Date	Batch #	Sold To	Product Des.	Amount used	Supplier	Lot #
2/18/15	TI21815	CM41598	Tea			
			Astragalus	2 oz	MRH	35851
			Schizandra	1 oz	MRH	45790
			Holy Basil	2 oz	MRH	CR4578

For batch numbers I use TI plus the date of manufacture for tinctures and TE plus date of manufacture for tea. This batch number is then added to the tincture or tea label. This ensures that if there is a recall from the supplier, that I can easily tract where the product was distributed and identify the item by the batch number. Another aspect of GMP compliance is the need to keep samples of products you make for two years with original batch number. I only do this with the items that I sell to the public. You also need to have a procedure and form in place for product complaints, this is an area I am still working on, although thankfully I have not received any, but that doesn't mean I can ignore it. I am sure that are other aspects of my GMP's that need to be tightened up. You can use this information as starting place of what needs to be put in place and then continue to revise and stay current on regulations.

Label Requirements: There are specific label requirements if selling to the public that I have outlined below and indicated if they are required or best practices. For custom formulas I include the client's name, date made, expiration date, batch number (client number) and contact information for my business. I also use shrink bands on my tinctures and clear mailing seals on my teas for tampering requirements as requested from my USDA inspector. There are also font size requirements on some of the items below. At the end of the article there are several resources listed for further information.

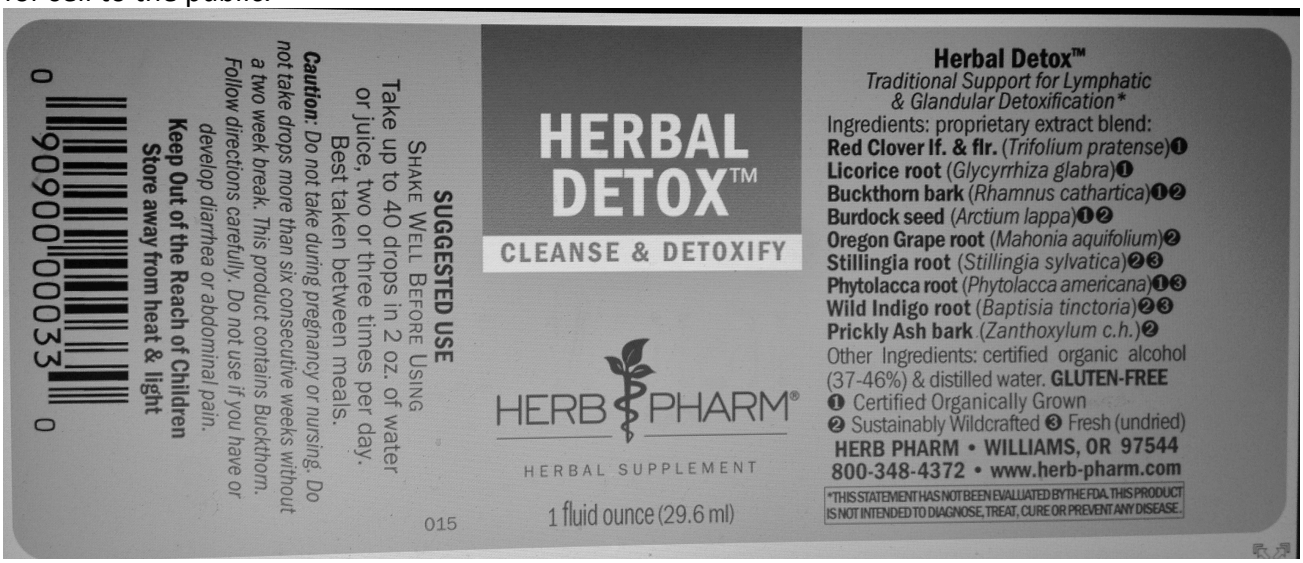
Required on label:

- "Herbal Supplement"(required)
- Net weight in oz and in brackets the grams if tea, or milligrams if tincture* Example "Net Wt. 1 fluid oz (29.6 ml) (required)
- Address of where it is manufactured, phone and email (required)
- Dates of expiration, or best used by (required)
- Directions on suggested use. (required) Example-Directions: Add 1 Tablespoon to 1 cup of boiling water, cover and let infuse for 10 minutes. On my tinctures: 60-90 drops 3 times a day.
- Daily value not established (best practices)
- "Keep out of reach of Children" (required)
- Ingredients listed from largest to smallest. Common names and parts (required) but it is advisable to use Latin (best practices) Common names used in commerce. http://www.ahpa.org/Default.aspx?tabid=357
- Tinctures- you need to state the dry herb/menstruum ration (required, ex. 1:3), rate of alcohol (50%, best practices).
- "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."(required, if there is a structure/function statement) For example, if you say that it supports "Healthy Function of the Immune System" then you need to use this statement.

- " Consult your doctor or pharmacist if you pregnant or are taking prescription medications regarding possible interactions. (best practices)
- How to store (best practices)
- Other general cautions (best practices)
- UPC codes (not required)

There is also a general requirement for site registration if selling to public: *All manufacturers, regardless of scale, must register their site with FDA. Site registration can be completed on the FDA website. An unregistered manufacturer will be ordered to cease manufacturing until registration has been completed. FDA also reserves the right to take legal action.*

Referencing other manufactures labels is also a great way to see what is correct. Herb Pharm does an excellent job of maintaining GMP standards and is excellent model to follow if manufacturing items for sell to the public.



Further Information

- **http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm238182.htm**
- PART 111 -- CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=111

Labeling requirements:

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=101&showFR=1&subpartNode=21:2.0.1.1.2.3
- http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm
- http://www.gancao.net/dshea

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