State-licensed Traditional Chinese Herbal Medicine Practitioners prescribe and can compound herbal dietary supplements within their state's Scope of Practice. It is your responsibility to comply with State and Federal regulations and guidelines established to ensure public safety and ensure the proper handling, compounding and labeling of every herb prescription for your patients. FDA's Dietary Supplement GMPs were finalized in 2007. However, the FDA regulates TCM Practitioners with "Discretionary Enforcement", if they compound a unique herb formula on a one-to-one basis with their own Patient.

1. **Dietary Supplement Health & Education Act (DSHEA) 1994**
2. **Dietary Supplement Good Manufacturing Practices (Final GMP) 2007**
3. **USP - Good Compounding Practice (GCP)**
4. **Nutrition Labeling and Education Act (NLEA) 2003**
5. **Food Allergen Labeling Act 2004**

Dietary Supplement Health & Education Act (DSHEA)

The *Dietary Supplement Health & Education Act* was passed in 1994. DSHEA established the current definitions for the terms "Dietary Supplement" and "Dietary Ingredient". It also established the Dietary Supplement Labeling Regulations. An important component of DSHEA is that it grants authority to the FDA to establish Good Manufacturing Practice regulations.

Dietary Supplement Good Manufacturing Practices (GMP)

With the passing of DSHEA, the FDA was given the authority to establish Good Manufacturing Practices for Dietary Supplements. They first began with a collaborated version that did not include Traditional Medicines and herb pharmacies in 1997. FDA published the official version of the first GMP for Dietary Supplements in 2003 and the final GMPs were published in 2007.

Who does the final GMP for Dietary Supplements involve?

Those who manufacture, package, label or hold Dietary Supplements

Good Compounding Practices (GCP)

The United States Pharmacopeia (USP) defines Good Manufacturing Practices and herb pharmacies have been regulated by USP since 1995. The Good Manufacturing Practices detail issues including personnel, facilities, equipment and utensils, operations, packaging and labeling, recordkeeping, etc. Following these guidelines helps to ensure the compounded preparations meet the Quality, Purity, Strength and Composition regulations.

Nutrition Labeling and Education Act (NLEA)

NLEA gives FDA authority to require nutrition labeling which includes nutrient content and health claims (Structure and Function claims).

Food Allergen Labeling Act

FDA requires all Dietary Supplement labels to list the inclusion of Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, and Soybeans.

What are Traditional Medicines?

Traditional medicines include Traditional Chinese Medicines, Chinese Herbal Medicines (CHM) and complimentary medicines like homeopathic medicines, herbs, herbal remedies, Traditional Indian Medicine (TIM) and Ayurveda.

What are the Legal repercussions of Non-Compliance?

Non-Compliance with FDA regulations can result in a fine or dissolution of your herb pharmacy and may result in the loss of your legal right to prescribe dietary supplements. Individual FDA inspectors are given the option to interpret Discretionary Enforcement as they choose to. Be aware of the consequences of prescribing herbal medicine within your state and federal regulations.

Professional and Ethical Conduct

We strongly propose that all TCM professionals practice herbal medicine at a high professional and ethical level. If you can not comply with all herb compounding regulations, it is recommended that you prescribe only finished products and do

not re-bottle or re-label these products. Choose a company who will promptly email you their GMP certification and COA (Certificate of Analysis) for every batch of every product when you need it.

In addition, we are legally required to report every SAE (Serious Adverse Event) to FDA's Medwatch program. A SAE concerns only a Patient who is hospitalized overnight.

What is a Dietary Supplement?

"A dietary supplement is a product taken by mouth that contains a "**dietary ingredient**" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement." (taken from www.fda.gov)

What are Dietary Ingredients?

"The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined both of the terms "dietary ingredient" and "new dietary ingredient" as components of dietary supplements. In order for an ingredient of a dietary supplement to be a "dietary ingredient," it must be one or any combination of the following substances:

- a vitamin
- a mineral
- an herb or other botanical
- an amino acid
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands)
- a concentrate, metabolite, constituent or extract.

A "new dietary ingredient" is one that meets the above definition for a "dietary ingredient" and was not sold in the U.S. in a dietary supplement before October 15, 1994." (taken from www.fda.gov)

What are Traditional Medicines?

"Traditional Medicine" includes Traditional Chinese Medicines (TCM) and Chinese Herbal Medicine (CHM). It also includes complimentary medicines, homeopathic medicine and herbs, herbal remedies and Traditional Indian Medicine (TIM) and Ayurveda.

What is Compounding?

Compounding is the method of combining two or more things, in this case dietary ingredients, to produce a new product typically intended to be more suitable for an individual's needs.

cGMP Final Rule Glossary

Actual yield
The quantity that is actually produced at any appropriate step of manufacture or packaging of a particular dietary supplement.

Batch
A specific quantity of a dietary supplement that is uniform, intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.

Batch number, **lot number**, or **control number**
Any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, and/or holding of a batch or lot of dietary supplements can be determined.

Component