

# White paper: Good herbal compounding and dispensing practices

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Prepared by the American Herbal Products Association



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# 1.0 Introduction

## Statement of purpose

This document was developed by the American Herbal Products Association (AHPA) to provide health care practitioners who prepare herbal formulas with a published reference that defines a standard of practice in herbal compounding and dispensing undertaken following one-on-one consultations with individuals. This document identifies herbal compounding and dispensing practices that pertain specifically to compounded herbal formulas. Individual establishments may provide differing levels of herbal compounding services and consequently only the relevant parts of this document apply to any given health care practice or establishment.

## Background

This document, “White paper: Good Herbal Compounding and Dispensing Practices,” has been created to assist herbal compounding and dispensing establishments in the development and maintenance of best practices in preparing herbal formulas that may then be dispensed following individual consultations.

This document is intended to ensure such herbal formulas are properly prepared and suggests record-keeping practices, which will in turn help to ensure the benefits and a reasonable expectation of safety of these herbal formulas for the individuals who use them.

Herbal products for human consumption are regulated as foods under the Federal Food, Drug, and Cosmetic Act as amended by the Dietary Supplement Health and Education Act of 1994,<sup>1</sup> as well as other laws adopted in the interim. However, an establishment at which herbal formulas are compounded on-site and dispensed to individual consumers falls into the definition of “retail food establishment.”<sup>2</sup> Retail food establishments are not required to register with FDA as food facilities.<sup>3</sup> Furthermore, retail food establishments are exempt from all requirements to create and maintain

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<sup>1</sup> Herbal products intended to diagnose, treat, cure, or prevent disease are in most cases (except where FDA has authorized a health claim) regulated as drugs and require FDA approval or inclusion in an over-the-counter (OTC) drug regulation for such use. Since very few herbal products have been approved by FDA as drugs or included in OTC drug regulations, in the U.S. herbal products are rarely marketed as anything other than dietary supplements, foods (e.g., teas) or, if used topically, as cosmetics.

<sup>2</sup> 21 CFR § 1.227 defines “retail food establishment” as “an establishment that sells food products directly to consumers as its primary function” and then goes on to define “selling food directly to consumers as its primary function” to mean that “the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.” It is to be noted that the annual monetary value of sales of non-food items and services has no relevance for purposes of this definition; the definition explicitly excludes non-food revenues from consideration in determining status as a “retail food establishment,”

<sup>3</sup> 21 CFR § 1.226(c) provides that retail food establishments are exempt from facility registration requirements.



records and make them available to FDA so long as the establishment does not sell food products to anyone other than consumers (i.e., not to other businesses).<sup>4</sup>

In the preamble to 21 CFR Part 111, the cGMP regulations that apply to dietary supplements, FDA indicates an intent to exercise “enforcement discretion” (i.e., to forgo enforcement of the dietary supplement cGMP regulations on health care practitioners) so long as practitioners have adequate professional training and dispense supplement products on the basis of one-on-one consultations, and the supplements dispensed have no known or suspected safety concerns.<sup>5</sup> The FDA’s discussion of this enforcement discretion is set forth below:

“We stated in the 2003 CGMP Proposal (68 FR 12157 at 12175) that we declined to exempt herbalist practitioners from the proposed rule. We continue to believe that the risks adulteration are not eliminated just because the practitioner is an herbalist, and therefore, such an exemption should not be included in this final rule. However, after further consideration, we have determined that it would be appropriate for us to consider the exercise of our enforcement discretion in deciding whether to apply the requirements of this final rule to certain health care practitioners, such as herbalists, acupuncturists, naturopaths, and other related health care providers. We find it noteworthy that the comments identified two potential safeguards that could support the exercise of our enforcement discretion on whether to apply the requirements of the final rule to certain practitioners: (1) Adequate training in the professional practice and (2) an individual client and practitioner relationship. For example, comments claimed that the practitioners receive adequate training to formulate dietary supplements and that they provide the dietary supplements to individuals in the course of a one-on-one consultation on the premises of the practitioner. One comment from a practitioner states that she received her training from an accredited 4-year university and it included didactic and clinical training in acupuncture and Chinese herbs. Another comment from an organization provides detailed training guidelines for practitioners, including 1,600 hours of training, 400 hours of which should include clinical work. Moreover, many comments also assert that the practitioners are different from dietary supplement manufacturers because they formulate the dietary supplements in the course of a one-on-one consultation at their premises. That enables them to ensure the formulations are made to meet the specific needs of the individuals. We believe that a one-on-one consultation by a practitioner who is adequately trained in their profession may not necessitate the same types of controls as we are establishing in this final rule for manufacturing activities that are on a larger scale. Such a practitioner may make some formulations in advance of the consultation and still make the formulations in very limited quantities for the individual client. We believe that it would be appropriate to consider the exercise of our enforcement discretion, on a case-by-case basis, to determine whether to apply the requirements of this final rule to such persons. We do not expect the number of those subject to the consideration of our enforcement discretion to be very large. Many products that are manufactured by practitioners would not necessarily be considered to be

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<sup>4</sup> 21 CFR § 1.327(e) provides that the records requirements of 21 CFR Subpart J apply to retail food establishments that sell food products to anyone other than consumers. Thus, the records requirements do *not* apply to retail food establishments that do *not* sell food products to anyone other than consumers (i.e., that sell exclusively to consumers rather than to businesses).

<sup>5</sup> 72 FR 34793 (June 25, 2007)



dietary supplements (e.g., certain products used by traditional Asian medicine practitioners). Further, we are not considering exercising our enforcement discretion with respect to practitioners who prepare batches of herbs and sell them to individual consumers without determining whether the dietary supplement is appropriate for each consumer's needs in a one-on-one personal consultation, or those that prepare batches of a dietary supplement for which there is a known or suspected safety concern.”<sup>5</sup>

The main emphasis of this guidance is on best practice for compounding of herbal formulas from herbs and other natural substances, either in combination or individually. The types of herbal formulas covered in this document include herbal formulas for use in various forms such as water decoctions, other liquid extracts, granules, powders or pills, as well as poultices, pastes, liniments, etc. The herbal compounding practices outlined in this document have a basis in standard cGMP rules such as 21 CFR Part 117 Subpart B (cGMPs for food) and 21 CFR Part 111 (cGMPs for dietary supplements) as well as the United States Pharmacopoeia (USP) USP-NF General Chapters for Compounding.<sup>6</sup>

## Scope

This document is designed for use by health care practitioners who compound and dispense herbal formulas for use following one-on-one consultations with specific individuals. The practices presented here are applicable in individual and group practices that maintain an herbal compounding establishment, as well as in compounding and dispensing establishments that are not directly affiliated with a specific practice but that prepare herbal formulations to meet the needs of one or more health care practitioners.

This document does not, however, provide training in the practice of any of these health care systems or disciplines, nor does it describe the technical performance of specific herbal compounding practices.

In addition, this document does not provide information for individuals or companies that manufacture herbal formulas and make these products available as dietary supplements for sale directly to consumers, or by way of intermediary businesses through any sales channel (e.g., through health food stores, groceries, health care practices, internet or mail order, etc.). Such manufacturers – including a practitioner that sells as little as a single herbal formula in a context that is not related to a one-on-one personal consultation – are subject to the GMP regulations in 21 CFR Part 111 as well as various other regulations governing product labeling, product claims, adverse event reporting, and other matters. Companies that process dietary supplements for sale to businesses (as opposed to consumers) are encouraged to engage qualified FDA legal counsel to ensure compliance with this robust regulatory structure. Establishments such as acupuncture clinics do not generally fall under these regulations unless they are selling products by any means outside of one-on-one individual consultations. Any health care practitioner or establishment of practitioners or formulators that has any question regarding

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<sup>6</sup> See USP-NF General Chapters for Compounding at <http://www.usp.org/usp-healthcare/professionals/compounding/compounding-general-chapters>



their status under the FDA's food establishment registration provisions or dietary supplement cGMPs should engage qualified FDA legal counsel to ensure compliance.

## Acknowledgements

This document was created through the joint efforts of AHPA staff and the AHPA Chinese Herbal Products Committee, which is composed of Chinese herbal product specialists as well as educators and health care practitioners.

Comments to this document can be directed to AHPA at its business office or via email, as follows:

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## Dedication

This document is dedicated to the memory of Al Stone, LAc, a well-known practitioner in the traditional Chinese medicine community. One of his many passions was the documentation of good dispensing practices for practitioners and Al's vision provided a foundation for the development of this document.

## Disclaimer

The information presented here is provided for guidance purposes only and not as legal advice. Health care practitioners who prepare herbal formulas for their clients are responsible for knowing, understanding, and conforming to all state, local, and federal laws and regulations that are relevant to their businesses, and for implementing practices that may go beyond those described here, as needed.

Any health care practitioner or establishment of practitioners or formulators that has any question regarding their status under the FDA's food establishment registration provisions or dietary supplement cGMPs should engage qualified FDA legal counsel to ensure compliance.

This document does not serve as a substitute for a health care practitioner's need to be knowledgeable about the herbal formulas which they compound.

These guidelines may be revised periodically as new information becomes available.



## 2.0 Definitions

The following definitions apply for purposes of terms used in this document.

*Adverse event* means any undesirable health-related event associated with the use of a product, whether or not considered causally related to the product. See also *Serious adverse event*.

*Complaint* means any communication (whether written, electronic, or oral) that expresses concern about or dissatisfaction with an herbal formula that may reflect inadequate product quality or safety or a deficiency in its formulation or dispensing.

*Contact surface* means any surface that contacts an ingredient or herbal formula, and those surfaces from which drainage onto the ingredient or herbal formula, or onto surfaces that contact the ingredient or herbal formula, occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, contact surfaces of equipment, and packaging.

*Control number* means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the herbal compounding, packaging, and labeling of an herbal formula can be determined.

*Decoction* means the cooking of an herb or an herbal formula for a specified length of time in water (or water and alcohol mixture) to produce an extract of soluble constituents of the herb(s).

*Enforcement discretion* means the ability of a regulatory body to determine how and when it will exercise its regulatory authority.

*Establishment* means a physical location where herbal formulas are supplied following one-on-one consultations. An establishment may contain an herbal compounding area.

*Herbal compounder* means the health care practitioner or other qualified person performing the process of combining ingredients into an herbal formula.

*Herbal compounding* means the activity of combining ingredients into an herbal formula.

*Herbal compounding area* means the work location in a professional office or other establishment that is dedicated to the compounding of herbal formulas.

*Herbal formula specification* means a file of each individually compounded herbal formula.

*In-process material* means any material that is blended, ground, extracted, sifted, or processed in any other way for subsequent use in the compounding of an herbal formula.

*Natural substance* means herbs, roots, barks, fruits, seeds, minerals, and animal substances.

*One-on-one consultation* means a health care practitioner's clinical relationship with an individual following which the practitioner may provide a recommendation for the use of one or more herbs or herbal formulas.

*Recommendation* means the act of a health care practitioner advising the use of a particular herb or herbal formula to an individual in the context of a "one-on-one" professional relationship.



*Serious adverse event* means an adverse event that:

- Results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; or
- Requires, based on a reasonable medical judgment, a medical or surgical intervention to prevent such an outcome.





## 3.0 Personnel

### 3.1 Training

Herbal compounding and dispensing establishments shall ensure that each person engaged in these functions has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.<sup>7</sup>

Herbal compounding and dispensing establishments shall maintain records of any training provided to employees for the performance of all assigned functions.

### 3.2 Personnel responsibilities

a) Herbal compounding and dispensing establishments shall take measures to exclude from any function any person who might be a source of microbial contamination due to a health condition through contact with any material, including ingredients, packaging components, in-process materials, herbal formulas, and contact surfaces used in herbal compounding. Such measures may include the following:

1. Excluding from working in any function that may result in contamination any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of ingredients, packaging components, in-process materials, herbal formulas, or contact surfaces, until the health condition no longer exists; and
2. Instructing personnel to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition that could result in microbial contamination of any ingredients, packaging components, in-process materials, herbal formulas, or any contact surface.

b) Personnel who work in any activity during which contamination of an ingredient, packaging components, herbal formula, or contact surface could occur shall use hygienic practices to the extent necessary to protect against such contamination of ingredients, packaging components, in-process materials, herbal formulas, or contact surfaces. These hygienic practices include the following:

1. Wearing outer garments in a manner that protects against the contamination of ingredients, packaging components, in-process materials, herbal formulas, or any contact surface;
2. Maintaining adequate personal cleanliness;
3. Washing hands thoroughly with soap (and sanitizing if necessary to protect against contamination with microorganisms):
  - Before starting work;
  - After using the restroom; and
  - At any other time when the hands may have become soiled or contaminated;

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<sup>7</sup> Adequate training may be demonstrated in different ways depending on the health care practitioner's specific discipline, for example by completion of a degree from an accredited institution of higher learning, by obtaining formal licensure for a relevant scope of health care practice, or by other adequate means.



4. Removing all unsecured jewelry and other objects that might fall into ingredients, packaging components, herbal formulas, equipment, or packaging, and removing hand jewelry that cannot be adequately cleaned during periods in which ingredients, packaging components, in-process materials, and herbal formulas are manipulated by hand. If hand jewelry cannot be removed, it shall be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against contamination of ingredients, packaging components, in-process materials, herbal formulas, or contact surfaces;
5. Using utensils or gloves to avoid direct hand contact in the handling of ingredients, packaging components, in-process materials, and herbal formulas. Gloves shall be suitable for food contact;
6. Wearing, where needed and appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;
7. Not storing clothing or other personal belongings in areas where ingredients, packaging components, in-process materials, herbal formulas, or any contact surfaces are exposed or where contact surfaces are washed;
8. Not eating food, chewing gum, drinking beverages, or using tobacco products in areas where ingredients, packaging components, in-process materials, herbal formulas, or any contact surfaces are exposed, or where contact surfaces are washed; and
9. Taking any other precautions necessary to protect against the contamination of ingredients, packaging components, in-process materials, herbal formulas, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.



## 4.0 Facilities

The health care practitioner who oversees the herbal compounding and dispensing establishment should ensure that the establishment supports the organized and hygienic management of ingredients, packaging components, in-process materials, and finished herbal formulas.

### 4.1 Compounding and dispensing areas

Areas designated for compounding and dispensing should have adequate space for the orderly placement of equipment and materials to prevent mixups among ingredients, containers, labels, in-process materials, and finished herbal formulas. The compounding area should be designed, arranged, used, and maintained to prevent cross-contamination. Compounding and dispensing areas should be well-lighted. Heating, ventilation, and air conditioning systems should be appropriately controlled and maintained. Storage areas should provide an environment suitably controlled to protect bulk ingredients and finished herbal formulas from contamination and degradation.

Potable water that meets the standards prescribed in the US Environmental Protection Agency's National Primary Drinking Water Regulations<sup>8</sup> shall be supplied for hand and equipment washing.

Herbal compounding areas should be maintained in a clean and sanitary condition. Trash, scrap, and other refuse in the herbal compounding area should be disposed of in a safe, sanitary, and timely manner.

Herbal compounding areas shall be cleaned thoroughly after each compounding of an herbal formula so as to prevent cross-contamination of subsequent formulas, including cross-contamination with allergenic ingredients.<sup>9</sup>

### 4.2 Toilet and hand-washing facilities

a) Herbal compounding establishments shall provide personnel with adequate, readily accessible toilet facilities.

1. Toilet facilities shall be maintained in a sanitary condition;
2. Toilet facilities shall be adequately stocked with toilet paper, soap, and single use paper towels or other drying devices;
3. Toilet facilities shall be kept in good repair at all times; and
4. Toilet facilities shall have signage advising personnel of the necessity of washing hands prior to returning to work.

b) Herbal compounding establishments shall provide personnel with adequate and convenient hand-washing facilities.

1. Hand washing facilities shall be provided with running hot water of suitable temperature;

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<sup>8</sup> 40 CFR Part 141

<sup>9</sup> For the purposes of this document, allergens are considered to be the major foods allergens identified in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). These allergens are: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.



2. Hand washing facilities shall be provided with effective hand cleaning and sanitizing preparations and single use paper towels or other drying devices;
3. Hand washing facilities shall be located at points in the establishment where good sanitary practices require personnel to wash or sanitize their hands.

## 4.3 Pest control

Herbal compounding and dispensing establishments should provide adequate pest control.

- a) Effective measures should be taken to exclude pests from the establishment and to protect against contamination of ingredients, packaging components, in-process materials, finished herbal formulas, and contact surfaces on the premises by pests.
- b) Insecticides, fungicides, or rodenticides shall not be used in or around the establishment, unless they are registered with EPA<sup>10</sup> and used in accordance with the label instructions. Effective precautions should be taken to protect against the contamination with pesticides of ingredients, packaging components, in-process materials, finished herbal formulas, or contact surfaces.

## 4.4 Sanitation

Herbal compounding and dispensing establishments should conduct all functions in accordance with adequate sanitation principles, including, but not limited to:

1. Cleaning and sanitizing equipment and utensils, containers, and other contact surfaces utilizing cleaning and sanitizing compounds that are labeled for use on food contact surfaces;
2. Minimizing airborne contamination, for example by keeping windows and doors closed in the herbal compounding area;
3. Using sanitary handling procedures;
4. Washing or cleaning ingredients that contain soil or other contaminants;
5. Using potable or purified water for compounding of herbal formulas that include water as an ingredient;
6. Using effective means to remove, destroy, or prevent the growth of microorganisms and prevent decomposition, such as boiling, freezing, refrigerating, or heating ingredients or herbal formulas that are susceptible to spoilage or microbial growth; and
7. Preventing cross-contamination and mixups between contaminated ingredients, in-process materials, finished herbal formulas, and uncontaminated items.

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<sup>10</sup> Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y



## 5.0 Equipment

### 5.1 Design and composition

- a) The equipment and utensils used for herbal compounding or dispensing of an herbal formula should be of appropriate design and capacity.
- b) The equipment should be maintained and stored in such a manner as to protect it from contamination, and if fixed in place should be located to facilitate its use, maintenance, and cleaning.
- c) The equipment and utensils should be of suitable composition such that the surfaces that contact ingredients are not reactive, additive, or absorptive and therefore will not affect or alter the safety, identity, strength, quality, or purity of the compounded herbal formula.

### 5.2 Inspection and calibration

- a) Equipment used in herbal compounding should be routinely inspected, calibrated as necessary, and checked to ensure proper performance.
- b) If required by state or local ordinance, weighing and measuring devices used in herbal compounding shall be legal for trade<sup>11</sup> and registered with the applicable local authority.
- c) Immediately prior to initiation of compounding of an herbal formula, the equipment should be inspected by the herbal compounder to determine its cleanliness and suitability for use.

### 5.3 Cleaning and sanitization

- a) After use, the equipment should be appropriately cleaned and sanitized.
- b) Equipment shall be cleaned thoroughly after each compounding of an herbal formula so as to prevent cross-contamination of subsequent formulas, including cross-contamination with allergenic ingredients.<sup>12</sup>

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<sup>11</sup> Weighing and measuring devices used in compounding practices must meet the requirements of the National Institute of Standards and Technology (NIST) Handbook 44, *Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices* (2012).

<sup>12</sup> For the purposes of this document, allergens are considered to be the major foods allergens identified in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). These allergens are: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.



## 6.0 General practices

### 6.1 Procedures

a) Procedures should be developed for operations such as herbal compounding, packaging and labeling, storage and dispensing of herbal formulas to ensure quality, safety, and uniformity in herbal compounding.

b) The herbal compounder should establish an herbal formula specification for each herbal formula to be compounded that includes the following:

1. The name, strength, and dosage form of the herbal formula to be compounded,
2. The intended ingredients of the herbal formula, and their amounts;
3. The herbal compounding process for the herbal formula, including the order of mixing, mixing temperatures or other environmental controls, such as the duration of mixing, and other factors pertinent to the replication of the preparation;
4. The required equipment and utensils;
5. The packaging and labeling to be used for the finished herbal formula;
6. Assigned beyond-use date; and
7. Storage requirements.

c) The herbal compounder should follow written procedures for the compounding of herbal formulas to assure that the finished herbal formulas meet the applicable specification. The compounder should accurately weigh, measure, and subdivide as appropriate.

d) The herbal compounder should check and recheck each procedure at each stage of the process to ensure that each weight or measure is correct as stated in the written herbal compounding procedures.

e) Each time the herbal formula is compounded, the herbal compounder should create an herbal compounding record (see Section 9.2).

f) Any modifications to the herbal formula specification made by the herbal compounder to meet individual needs should be recorded in the herbal compounding record.

### 6.2 Ingredients

a) Ingredients of high quality should be used and may be obtained from a source deemed acceptable and reliable in the professional judgment of the herbal compounder.

b) The herbal compounding establishment should document the authenticity of ingredients used in herbal compounding through one or more of the following means:

- Identification of herbal ingredients through organoleptic, macroscopic, or microscopic analysis by adequately trained personnel;
- Certificates of analysis<sup>13</sup> provided by ingredient vendors that include documentation as to how the authenticity of the ingredient was determined ; and

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<sup>13</sup> Health care practitioners may consider requiring certificates of analysis that document the ingredient's compliance with applicable cGMPs for food or dietary supplement uses, or botanical drug uses for ingredients manufactured outside the US.



- Other appropriate means provided in compendial monographs or other authoritative references.

c) The herbal compounder shall not use ingredients that are prohibited from the market by FDA for public health reasons.

d) Ingredients should be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

e) If an ingredient is transferred from the original container to another container (e.g., a powder is taken from the original container, weighed, placed in a new container, and stored in the new container), the new container should be identified with the ingredient name, weight or measure, the lot or control number, the expiration or beyond-use date, and the transfer date.

f) The herbal compounder may establish appropriate beyond-use dates determined either from appropriate testing, peer-reviewed scientific literature, or traditional practice and training.

### 6.3 Quality control

a) The herbal compounder should have established written procedures that describe the tests or examinations to be conducted on the compounded herbal formula (e.g., the degree of weight variation among capsules) to assure uniformity and integrity of compounded herbal formulas.

b) Appropriate control procedures should be established to monitor the output and to validate the performance of those herbal compounding processes that may cause variability in the final herbal formula, such as capsule weight variation and adequacy of mixing.



## 7.0 Herbal compounding practices

The herbal compounder should use the following steps to minimize error in herbal compounding practices. Critical processes should be reviewed to ensure that these procedures, when used, consistently result in the expected qualities in the finished herbal formula.

1. Compound only one herbal formula at a time in a specified herbal compounding area.
2. Perform necessary calculations to establish the amounts of ingredients needed and have the calculations double-checked.
3. Identify equipment and utensils needed.
4. Don the proper attire and wash hands.
5. Clean the herbal compounding area and needed equipment.
6. Assemble all necessary ingredients to compound the herbal formula.
7. Compound the preparation following the herbal formula specification.
8. Assess weight variation, adequacy of mixing, etc. of the herbal formula as appropriate.
9. Document each step in the compounding process herbal formula specification, as well the control number assigned to the cycle of preparation.
10. Package and label the product container(s) as described in Section 8.0.
11. Sign and date the herbal compounding record (see Section 9.2) affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity, and purity.
12. Thoroughly and promptly clean and sanitize all equipment, and store properly.
13. Counsel the individual or the individual's agent about proper use, storage, and potential side effects of the herbal formula at the time of dispensing or provide a label or labeling providing such information.





## 8.0 Packaging and labeling

### 8.1 Packaging components

- a) The herbal compounder should ensure that the packaging components selected to dispense the herbal formula meet the following criteria:
1. Are made of clean materials that are not reactive, additive, or absorptive.
  2. Are of suitable material so as not to alter the quality, strength, or purity of the compounded herbal formula, and are suitable for food contact.
  3. Are appropriate for the physical and chemical properties of the compounded herbal formula.
- b) Packaging components should be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.
- c) Packaging components should be stored in such a way as to permit inspection and cleaning of the work area.

### 8.2 Labeling

- a) The herbal formula label shall include all information required by state and federal law, as applicable, and accepted standards of practice, including the presence of any major food allergens.<sup>14</sup>
- b) Herbal formulas should be labeled at a minimum with the following:
1. Individual's name
  2. Herbal formula name;
  3. Dosage form and strength;
  4. Preparation date;
  5. Dispensing date;
  6. Name and address of health care practitioner;
  7. Control number; and
  8. Assigned beyond-use date, if any is relevant.
- c) In addition, the following should be provided on herbal formula labels or in documentation accompanying their dispensing:
1. A complete list of ingredients (including inactive);
  2. Declaration of alcohol in a liquid preparation, if present;
  3. Recommendations for use;
  4. Possible side-effects, as applicable; and
  5. Point of contact for the herbal compounder, if different than the health care practitioner.
- d) The herbal compounder should examine the herbal formula for correct labeling after completion of the herbal compounding process.

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<sup>14</sup> For the purposes of this document, allergens are considered to be the major food allergens identified in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). These allergens are: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.



e) The labeling information specified in Sections 8.2 b) and c) should be provided in a language and form of nomenclature that is understandable to the individual to whom the herbal formula is intended to be dispensed.

### **8.3 Storage**

Storage conditions for herbal formulas should be dictated by their composition and susceptibility to microbial growth, e.g., stored in a clean, dry place under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer).



## 9.0 Records

The herbal compounder should maintain records, including but not limited to, a copy of the health care practitioner recommendation, herbal formula specification (see Section 6.1), herbal compounding and dispensing records.

The herbal formula specification provides consistent instructions for preparing the herbal formula, and the herbal compounding record documents the actual ingredients in the preparation and the person responsible for the herbal compounding activity. These records shall be retained for the period of time that is required within the jurisdiction of the health care practitioner's activity, or, if no formal requirement exists, for at least one year after any beyond- use dating on the herbal formula or one year if there is no such dating.

### 9.1 Herbal compounding record

The herbal compounding record should contain the following information:

1. Individual's name for the cycle of preparation;
2. Name and strength of the compounded herbal formula;
3. Amounts, sources, and lot numbers of ingredients and packaging components used (as applicable);
4. Any modification(s) to the herbal formula specification made during herbal compounding to meet individual needs;
5. Total quantity or number of dosage units compounded;
6. Name of the health care practitioner recommending the herbal formula;
7. Name of the person who compounded the herbal formula (if different than the health care practitioner);
8. Date of herbal compounding; and
9. Control number and if applicable, the assigned beyond-use date.

### 9.2 Dispensing record

The dispensing record should contain the following information:

1. Individual's name;
2. Herbal formula dispensed;
3. Control number;
4. Date of dispensing;
5. Name of the health care practitioner recommending the herbal formula;
6. Name of the dispensing staff; and
7. Copy of the recommendations for use provided to the individual.



## 10.0 Complaints and recalls

### 10.1 Complaints

a) Herbal compounding establishments should establish written procedures describing the handling of all complaints received regarding a compounded herbal formula.

b) A qualified person should:

1. Review all complaints to determine whether the complaint involves a possible failure of a compounded herbal formula to meet any of its specifications, or any other requirements, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury.
2. Investigate any complaint that involves a possible failure of a compounded herbal formula to meet any of its specifications, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury.
3. Review and approve decisions about whether to investigate a complaint and review and approve the findings and follow-up action of any investigation performed.

c) The review and investigation of the compounded herbal formula should extend to all related herbal compounding and relevant records. Related herbal compounding may include, but is not limited to, prior instances of the compounding of the same herbal formula, other herbal formulas processed on the same equipment or during the same time period, or other herbal formulas produced using the same lots of ingredients or packaging components.

d) The herbal compounding and dispensing establishment should keep a written record of the complaint and where applicable its investigation, including:

1. Name and strength, grade, or other key characteristics of the compounded herbal formula;
2. Control number of the herbal formula;
3. Date the complaint was received and the contact information for the complainant, if available;
4. Nature of the complaint including, if known, how the herbal formula was used;
5. Reply to the complainant, if any;
6. Findings of the investigation and follow-up action taken when an investigation is performed;
7. Name(s) of the qualified person(s) who review the complaint and investigate the complaint as applicable; and
8. Name of qualified person who reviewed and approved the decision about whether to investigate a complaint and who reviewed and approved the findings and follow-up action of any investigation performed.

e) Complaint records should be retained for one year past the beyond use date of the herbal formula affected, or for one year past the date of receipt of the complaint, whichever is longer.

### 10.2 Serious adverse events

a) Compounding establishments should establish a procedure for complaints reporting a serious adverse event. The procedure should address whether the serious adverse event:



1. Requires reporting to FDA<sup>15, 16</sup>;
2. Should be reported to the health care practitioner of record for the individual reported to have experienced the serious adverse event, if known;
3. Should be reported to the vendor(s) who supplied the herbal formula or its ingredients and packaging components to the herbal compounding establishment, as applicable; and
4. Requires a recall.

## 10.3 Recall procedures

a) Herbal compounding establishments should establish a policy for recalling a compounded herbal formula that has been shown to present a reasonable probability that the use of the herbal formula will cause serious adverse health consequences. This policy shall include:

1. Factors which necessitate a recall;
2. Personnel responsible for a recall; and
3. Notification protocols, including notification to FDA.

b) Herbal compounding establishments should establish a policy for communicating a recall of an herbal formula that has been shown to present a reasonable or a remote probability that the use of or exposure to the herbal formula will cause serious adverse health consequences, or could cause temporary or medically reversible adverse health consequences. This policy should include:

1. A mechanism to contact all individuals who have, or could have, obtained the compounded herbal formula from the operation;
2. A mechanism to contact the vendor(s) who supplied the recalled herbal formula or its ingredients and packaging components to the establishment, as applicable; and
3. Information on the return or destruction of any recalled herbal formula.

c) Herbal compounding establishments should dispose of returned recalled herbal formulas in a manner that ensures that it cannot be not be used by any other person.

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<sup>15</sup> Serious adverse events should be considered in accordance with FDA's *Guidance for Industry Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act*, available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/UCM381121.pdf>.

<sup>16</sup> If an individual reports a serious adverse event associated with a dietary supplement product provided by the health care practitioner, the practitioner should report the serious adverse event to the dietary supplement marketer as well as to the FDA utilizing the FDA MedWatch system.

