Guidance: Best TCHM Compounding and Dispensing Practices

April 2017

Prepared by the American Herbal Products Association

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

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1.0 Introduction

Statement of Purpose

In 2016, at the request of the Chinese Medicine profession, the American Herbal Products Association (AHPA) and the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) developed guidelines and published reference for the state-licensed and nationally-certified practitioners of Traditional Chinese Herbal Medicine (TCHM) which defines the best practices in herbal compounding and dispensing following a one-on-one consultation with their own patient.

Background

These guidelines have been created to reduce the risk of potential adverse events related to herbal medicine and help ensure public safety. From the medical, legal, and ethical perspectives, when custom herbal prescriptions are properly compounded and record-keeping practices followed, patients can be assured of the benefits with a reasonable expectation of safety.

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 forbear enforcement of the dietary supplement cGMP regulations on health care practitioners) **ONLY if** 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.**[1]

TCHM Practitioners compounding and dispensing herbal prescriptions should be aware that adherence to these expectations supports the current regulatory status of compounding and dispensing establishments with regard to preparing herbal prescriptions, as the FDA considers enforcement discretion with respect to that agency's cGMPs for dietary supplements. FDA states that **"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"** and as such **"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."**[5]

The main emphasis of this guidance is on best practice for compounding of herbal prescriptions from herbs and other natural substances, either in combination or individually. The types of herbal prescriptions covered in this document include herbal prescriptions 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 guidance have a basis in **FDA cGMP rules** such as

[1] 72 FR 34752.

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.[2]

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,[3] as well as other laws adopted in the interim. However, health care clinics at which herbal prescriptions are compounded on-site and dispensed to their own individual patient falls into the definition of "retail food establishment."[4] Retail food establishments are not required to register with FDA as food facilities.[5] Furthermore, retail food establishments are exempt from all requirements to create and maintain 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).[6]

Scope

This guidance is designed for use by TCHM Practitioners who custom compound and dispense herbal prescriptions for use following one-on-one consultations with their own patient. The best practices presented here are applicable in individual and group practices that maintain an herbal compounding pharmacy.

This guidance 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 guidance does not provide information for individuals or companies that manufacture herbal products 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 prescription 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)

[2] See USP-NF General Chapters for Compounding at http://www.usp.org/usp-healthcare-professionals/compounding/compounding-general-chapters

[3] 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 for such use. Since very few herbal products have been approved by FDA as drugs, 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.

[4] 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,"

[5] 21 CFR § 1.226(c) provides that retail food establishments are exempt from facility registration requirements.

[6] 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.

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 TCHM Practitioner 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.

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 TCHM Practitioner . One of his many passions was the documentation of best compounding and dispensing practices for the TCHM community 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. TCHM Practitioners who prepare herbal prescriptions for their own patients 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 TCHM Practitioner 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 guidance document does not serve as a substitute for a TCHM Practitioner's requirement to be knowledgeable about the herbal prescriptions 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 best practices guidance.

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

Certificates of Analysis document the ingredient's compliance with applicable cGMPs for food or dietary supplement uses, or botanical drug uses for ingredients manufactured outside the US.

Complaint means any communication (whether written, electronic, or oral) that expresses concern about or dissatisfaction with an herbal prescription 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 prescription, and those surfaces from which drainage onto the ingredient or herbal prescription, or onto surfaces that contact the ingredient or herbal prescription, 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 prescription can be determined.

Decoction means the cooking of an herb or an herbal prescription 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 that the FDA will exercise its regulatory authority **ONLY if** TCHM 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.

Establishment means a physical location where herbal prescriptions are compounded following one-on-one consultations.

Herbal Compounder means the TCHM Practitioner or other qualified person performing the process of combining ingredients into an herbal prescription.

Herbal Compounding means the activity of combining ingredients into an herbal prescription.

Herbal Compounding Area means the work location in a TCHM professional clinic that is dedicated to the compounding of herbal prescriptions.

Herbal Pharmacy does not incorporate pharmaceutical drugs. A Herbal Pharmacy only uses Natural Substances.

Herbal Prescription is **not** a Prescription with pharmaceutical drugs. An Herb Prescription is created by a state-licensed and nationally-certified TCHM practitioner.

Herbal Prescription Specification means a file of each individually compounded herbal prescription.

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 TCHM Practitioner's clinical relationship with their patient following which the TCHM Practitioner may provide a recommendation for the use of one or more herbs or herbal prescriptions.

Recommendation means the act of a TCHM Practitioner advising the use of a particular herb or herbal prescription to their Patient 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.[7]

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 prescriptions, 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 prescriptions, 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 prescriptions, or any contact surface.

b) Personnel who work in any activity during which contamination of an ingredient, packaging components, herbal prescriptions, 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 prescriptions, 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 prescriptions, 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;

[7] Adequate training may be demonstrated in different ways depending on the TCHM 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 prescriptions, equipment, or packaging, and removing hand jewelry that cannot be adequately cleaned during periods in which ingredients, packaging components, in-process materials, and herbal prescriptions 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 prescriptions, or contact surfaces;
5. Maintaining gloves used in handling ingredients, packaging components, in-process materials, herbal prescriptions in an intact, clean, and sanitary condition. The gloves shall be of an impermeable material;
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 prescriptions, 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 prescriptions, 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 prescriptions, 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 TCHM Practitioner who oversees the Herbal Compounding and Dispensing establishment shall ensure that the establishment supports the organized and hygienic management of ingredients, packaging components, in-process materials, and finished herbal prescriptions.

4.1 Compounding and Dispensing Areas

Areas designated for compounding and dispensing shall have adequate space for the orderly placement of equipment and materials to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished herbal prescriptions. The compounding area shall be designed, arranged, used, and maintained to prevent cross-contamination. Compounding and dispensing areas shall be well-lighted. Heating, ventilation, and air conditioning systems shall be appropriately controlled and maintained. Storage areas shall 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[8] shall be supplied for hand and equipment washing.

Herbal compounding areas shall 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 herbal compounding so as to prevent cross-contamination with allergenic ingredients.[9] (milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans)

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 water of suitable temperature;
2. Hand washing facilities shall be provided with effective hand cleaning and sanitizing preparations and single use paper towels or other drying devices;

[8] 40 CFR Part 141

[9] For the purposes of this guidance, allergens are considered to be the eight major food allergens identified in the FDA's Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

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 shall provide adequate pest control.

a) Effective measures shall 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[10] and used in accordance with the label instructions. Effective precautions shall be taken to protect against the contamination with pesticides of ingredients, packaging components, in-process materials, finished herbal prescriptions, or contact surfaces.

4.4 Sanitation

Herbal compounding and dispensing establishments shall 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;
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 prescriptions 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 prescriptions that are susceptible to spoilage or microbial growth; and
7. Preventing cross-contamination and mix-ups between contaminated ingredients, in-process materials, finished herbal prescriptions, and uncontaminated items.

[10] 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 prescription shall be of appropriate design and capacity.

b) The equipment shall 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 shall 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 prescription.

5.2 Inspection and calibration

a) Equipment used in herbal compounding shall 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[11] and registered with the applicable local authority.

c) Immediately prior to initiation of compounding of an herbal prescription, the equipment shall be inspected by the herbal compounder to determine its cleanliness and suitability for use.

5.3 Cleaning and sanitization

a) After use, the equipment shall be appropriately cleaned and sanitized.

b) Where cross-contamination with allergens[12] is possible (e.g., where equipment has been used with an allergenic substance), the equipment shall be thoroughly cleaned prior to use for the next herbal prescription; alternately, dedicated equipment may be used for the allergen-containing ingredients and products.

[11] 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).

[12] For the purposes of this guidance, allergens are considered to be the eight major foods allergens identified in FDA's Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

6.0 General Practices

6.1 Procedures

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

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

1. The name, strength, and dosage form of the herbal prescription to be compounded,
2. The intended ingredients of the herbal prescription, and their amounts;
3. The herbal compounding process for the herbal prescription, 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 prescription;
6. Assigned beyond-use date; and
7. Storage requirements.

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

d) The herbal compounder shall 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 prescription is compounded, the herbal compounder shall create an herbal compounding record (see Section 9.2).

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

6.2 Ingredients

a) Ingredients of high quality shall 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 shall 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[13] provided by ingredient vendors; and

[13] TCHM 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 shall 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 shall 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 shall have established written procedures that describe the tests or examinations to be conducted on the compounded herbal prescription (e.g., the degree of weight variation among capsules) to assure uniformity and integrity of compounded herbal formulas.

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

7.0 Herbal Compounding Practices

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

1. Compound only one herbal prescription 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 prescription.

7. Compound the preparation following the herbal prescription specification.

8. Assess weight variation, adequacy of mixing, etc. of the herbal prescription, as appropriate.

9. Document each step in the compounding process herbal prescription 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 patient or the patient's agent about proper use, storage, and potential side-effects of the herbal prescription at the time of dispensing.

8.0 Packaging and Labeling

8.1 Packaging components

a) The herbal compounder shall ensure that the packaging components selected to dispense the herbal prescription 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 prescription, and are suitable for food contact.
3. Are appropriate for the physical and chemical properties of the compounded herbal prescription.

b) Packaging components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is prescribed first.

c) Packaging components shall be stored in such a way as to permit inspection and cleaning of the work area.

8.2 Labeling

a) The herbal prescription 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.[14]

b) Herbal prescription should be labeled at a minimum with the following:

1. Patient's name
2. Herbal prescription name;
3. Dosage form and strength;
4. Preparation date;
5. Dispensing date;
6. Name and address of TCHM practitioner;
7. Control number; and
8. Assigned beyond-use date, if any is relevant.

c) In addition, the following shall be provided on herbal prescription 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 TCHM practitioner.

d) The herbal compounder shall examine the herbal prescription for correct labeling after completion of the herbal compounding process.

[14] For the purposes of this guidance, allergens are considered to be the eight major foods allergens identified in FDA's Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

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

8.3 Storage

Storage conditions for herbal prescriptions shall 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 shall maintain records, including but not limited to, a copy of the TCHM 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 prescription or one year if there is no such dating.

9.1 Herbal Compounding Record

The Herbal Compounding Record shall contain the following information:

1. Patient's name for the cycle of preparation;
2. Name and strength of the compounded herbal prescription;
3. Amounts, sources, and lot numbers of ingredients and packaging components used (as applicable);
4. Any modification(s) to the herbal prescription specification made during herbal compounding to meet the patient's needs;
5. Total quantity or number of dosage units compounded;
6. Name of the TCHM practitioner recommending the herbal prescription;
7. Name of the person who compounded the herbal prescription (if different than the TCHM 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 shall contain the following information:

1. Patients name;
2. Herbal prescription dispensed;
3. Control number;
4. Date of dispensing;
5. Name of the TCHM Practitioner recommending the herbal prescription;
6. Name of the dispensing staff; and
7. Copy of the recommendations for use provided to the patient.

10.0 Complaints and Recalls

10.1 Complaints

a) Herbal compounding clinics shall establish written procedures describing the handling of all Complaints received regarding a compounded herbal prescription.

b) A qualified person shall:

1. Review all Complaints to determine whether the complaint involves a possible failure of a compounded herbal prescription 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 prescription 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 prescription shall extend to all related herbal compounding and relevant records. Related herbal compounding records may include, but is not limited to, prior instances of the compounding of the same herbal prescription, other herbal prescriptions processed on the same equipment or during the same time period, or other herbal prescriptions produced using the same lots of ingredients or packaging components.

d) The herbal compounding and dispensing clinic shall 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 prescription;
2. Control number of the herbal prescription;
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 prescription 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 shall be retained for one year past the beyond-use date of the herbal prescription affected, or for one year past the date of receipt of the Complaint, whichever is longer.

10.2 Serious Adverse Events

a) Compounding establishments shall establish a procedure for Complaints reporting a Serious Adverse Event. The procedure shall address whether the Serious Adverse Event:

1. Requires reporting to FDA[15, 16];
2. Shall be reported to the TCHM Practitioner of record for the Patient reported to have experienced the Serious Adverse Event, if known;
3. Shall be reported to the Vendor(s) who supplied its ingredients and packaging components to the herbal compounding clinic, as applicable; and
4. Requires a Recall.

10.3 Recall Procedures

a) Herbal compounding clinics shall establish a policy for recalling a compounded herbal prescription that has been shown to present a reasonable probability that the use of the herbal prescription 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 clinics shall establish a policy for communicating a Recall of an herbal prescription that has been shown to present a reasonable or a remote probability that the use of or exposure to the herbal prescription 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 prescription from the operation;
2. A mechanism to contact the Vendor(s) who supplied the recalled ingredients and packaging components to the establishment, as applicable; and
3. Information on the return or destruction of any recalled herbal prescription.

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

[15] Serious Adverse Events shall 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/GuidanceDocumentsRegulatory/Information/DietarySupplements/UCM381121.pdf

[16] If a Patient reports a Serious Adverse Event associated with an herbal prescription provided by their TCHM Practitioner, the TCHM Practitioner shall report the Serious Adverse Event to the dietary supplement Vendor as well as to the FDA utilizing the FDA MedWatch system.