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In the Unlikely Event of an FDA Recall … No News Has Been Good News

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East Asian herb product manufacturers have practiced impeccable diligence by complying with current Good Manufacturing Practices (cGMP) and providing the practitioner community certificates of analyses that detail laboratory testing results for things like heavy metals and toxic elements. Practitioners that contract with FDA cGMP compliant companies have benefited from products they can trust.

However, to help ensure patients have optimal access to product safety data, practitioners need to get involved in the final process of product distribution. To do this, practitioners need to ensure all herb prescription labels bear tracking information that connects the product ingredients with relative lot numbers, in the unlikely event of an FDA recall. This is especially the case when a practitioner creates a custom herb-prescription with a custom label.

Ethical Practice

Unlike a typical retail product, herb-prescriptions are *prescribed* by State-Licensed Nationally-Certified practitioners of East Asian medicine. A prescribing practitioner bears years of formal education and a great deal of responsibility. Sourcing products from quality suppliers and maintaining proper records is an often unspoken but necessary ethical guideline for practitioners.

Records Keeping

Every herb-prescription must have a lot number tracing back to the source of its herbal components. Additionally, every herb-prescription shall be recorded so that, in the unlikely event of an FDA recall of a product or product component, the patient can be immediately notified.

The FDA guidelines for Good Manufacturing Practices discusses the role of lot numbers for dietary supplements under a section named “Records Keeping.” Products are coded and tracked throughout their journey from farm to table, making sure that there is a way to isolate issues when they arise from monitoring products to suppliers. This orderly process is designed to swiftly address the source of contamination, and cease the consumption of products as soon as they are known to be dangerous.

The FDA defines dietary supplement codes as follows, 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.”[1]

Lot – “a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications for identity, purity, strength, and composition; or, in the case of a dietary supplement produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.”

Where Recalls Often Begin

State departments of health track Lot Numbers from products surrendered by sick patients. Then manufacturers associated with the lot numbers are contacted, and required to test their other products. Once a complete list of lot numbers is gathered from contaminated products, the list is given to distributors, retailers and posted for consumers to attempt to remove potentially dangerous products from consumption.

The messaging for consumers is simple, “Consumers who may be in possession of potentially contaminated products are advised not to consume products labeled with the … product descriptions and lot codes. (AHPA 2018).” Refunds should be available in the case of a recall to further resist consumer temptation to consume a purchased product.

When an Audit Occurs

If a recall occurs, a facility (such as an herb-compounding pharmacy) shall conduct a full audit of all its manufactured products to ensure that cross-contamination isn’t an issue, and to guarantee that all the known contaminated product is effectively destroyed.

Crises Management Prevention Plan

Practitioners that wish to have a crisis management prevention plan in place if there were ever to be an FDA recall of an herb-prescription might follow the following summarized list:

Review Current Suppliers Periodically

- Are they cGMP compliant?
- Do they provide certificates of analyses?
- Have they had any failures to meet FDA requirements?

Check Current Inventory

- Are all the finished products (patents) labeled with lot numbers?
- Do the products offer complete ingredient labels?
- Are the manufacturer’s address and phone number on the bottle?

Manage Records

- Do you keep records of date ranges of when you receive lot numbers?
- Do you notate each lot number of each herb-product in every patient file?
- Do you have a system for searching your patient database to contact a patient in the unlikely event of an FDA recall?

Patient Education

- Do you educate your patients not to attempt to purchase a similar prescription from an unknown online retailer?
- Do you confirm that only the patient named on the label of the herb-prescription consumes the herbal product?
- Do you inform your patient to seek medical attention if a serious adverse event occurs after consuming an herbal product?

Recalls are unfortunately an inevitable and common problem in the Food and Drug market. East Asian herbal medicine products haven’t been lucky to avoid being implicated; they have a very clean processing method by design. It is a harsh environment for things like salmonella and E-coli to survive. A practitioner with an unclean compounding space is likely the culprit if something gets into a custom herb-prescription.

In cases like that, a recall may be isolated to one clinic. Things that can’t be sterilized from prescriptions such as toxins and heavy metals might also trigger an FDA recall. Fortunately, modern

testing equipment found in the leading suppliers of East Asian herbal medicine products identifies the presence long before the herbs are processed. The final product from manufacturing is also tested once again for potential contaminants, and any product that fails is rejected.

Speaking to patients about these aspects is a great way to illustrate the modern herbal-pharmacy that brings the traditional medical wisdom and the modern safety design together for the benefit of the patient.

Reference

1. U.S. Food & Drug Administration. Dietary Supplements. *FDA*, 2018.

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