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LIFE SCIENCES AND MEDICAL PRODUCTS ALERT

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A Primer on Bringing Traditional Chinese Medicine to the U.S. Market

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Healthcare consumers are increasingly turning to alternative medicine as a potential source for medical treatment. Traditional Chinese Medicine (or TCM) is one form of alternative medicine that is increasingly used in the U.S. TCM dates back nearly 5,000 years to ancient China and encompasses a diverse array of treatments. Common TCM treatments include yoga, massage, acupuncture, and herbal remedies. Some TCM techniques are used by practitioners without regulation by the United States Food and Drug Administration (the "FDA"), while medical products are typically regulated by the FDA. Producers of TCM products must know how their TCM product is regulated by the FDA before deciding whether to market or sell the TCM product in the U.S.

TCM products are not exempt from FDA regulation and are subject to the same oversight and control from the FDA as Western medical products. The first step in determining how U.S. regulations might apply to a TCM product is to assess how it is classified under the law. Under FDA regulations, the TCM product may be classified as a drug, device, food, food additive, dietary supplement, cosmetic, or biological product depending on its use and purpose. This determination is not always easy.

The following chart provides a brief summary of the different product classifications that might apply to a TCM product:

PRODUCT TYPE	KEY REGULATORY CHARACTERISTICS	EXAMPLE (depending on the claims being made for the product)
Drug	• Products in the official pharmacopeia, homeopathic pharmacopeia or formulary; and • products intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease; and • products (other than food) intended to affect the structure or any function of the body	Herbal product intended to treat arthritis

Chart continued on next page

PRODUCT TYPE	KEY REGULATORY CHARACTERISTICS	EXAMPLE (depending on the claims being made for the product)
Device	Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, including any component, part or accessory, which is: • in the official pharmacopeia or formulary; or • intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease; or • intended to affect the structure or any function of the body; and which does not achieve its primary intended purposes through chemical action and which is not dependent on being metabolized to achieve its primary purpose.	Acupuncture needles
Food	Articles used for food or drink, chewing gum and components thereof.	Juice Therapy (without claims that would make it subject to the drug definition)
Food Additive	Any substance that becomes a component or otherwise affects the characteristics of food not generally recognized to be safe for its intended use.	Botanicals or enzymes added to foods
Dietary Supplement	Product intended to supplement the diet that contains certain dietary ingredients intended for ingestion not as a conventional food or as the sole item of a meal and is labeled as a dietary supplement.	Cranberry tablets labeled to maintain the health of the urinary tract
Cosmetic	Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or applied to the body for cleansing, beautifying, promoting attractiveness or altering the appearance and any components of such products (not soap).	Moisturizer for massage
Biological Product	A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product or arsphenamine or derivative applicable to the prevention, treatment, or cure of a disease or condition.	Probiotic that contains bacteria and animal-derived extracts

As an example, the FDA discussed in its draft guidelines[1] to the TCM industry a hypothetical TCM herbal product with an intended use of treating arthritis in humans. Under existing law, because the intended use of the herbal product is to "diagnose, cure, mitigate, treat or prevent disease" it is a drug as that term is defined within the regulations. The hypothetical herbal product could be a "new drug" under the regulations if it is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in labeling." A new drug is subject to significant regulatory requirements before it can be legally marketed. These additional requirements add significant lead time and money to getting a TCM product to market, but must be complied with to reach the hands of U.S. consumers.

Once it is determined how a TCM product will be classified, the next step is to understand what requirements will be imposed on the product by the U.S. Federal Food, Drug & Cosmetic Act and the Public Health Service Act. These requirements range from registration, product listing, pre-market review, labeling, post-marketing reporting and good manufacturing practices.

Nerac[2], a research and advisory firm, commented that in light of the possible regulatory requirements, regulatory and business strategies should be carefully planned in tandem. Meeting various regulatory requirements will strongly influence a company's launch plan and timeline. For example, dietary supplements consumed orally may have a faster route to market than other product categories. Similarly, limiting product claims (if any) to how the product affects the structure and function of the body in terms that do not imply a treatment or cure for any disease may also facilitate a getting a product to market. Companies should also be aware that, unfortunately, even a thousand years of use outside the United States is not an adequate justification by itself to establish that a product is safe and thus animal testing may be required.

The ramifications for not complying with U.S. regulations are serious. The FDA's primary administrative enforcement remedy is a product recall. FDA product recalls require that manufacturers and distributors remove or correct products that are non-compliant with applicable regulations. Additionally, the FDA may seek other administrative actions against non-compliant producers and distributors such as import refusals, debarment and withdrawal of product approvals. The Federal Food, Drug & Cosmetic Act provides the FDA, in conjunction with the U.S. Department of Justice, an array of judicially enforceable remedies against non-compliant producers and distributors including injunctions, criminal and civil penalties, imprisonment, and product seizure. Specific to policing TCM products, the FDA enforcement division issued a warning letter threatening extrajudicial enforcement against a Chinese firm selling TCM that was purported to remedy the H1N1 Flu virus. In that

1 "Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration" at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm145405.pdf

2 See www.nerac.com

case[3], the FDA determined that the TCM Discovery Herbal Teas being sold over the internet were not approved, cleared, or otherwise authorized by FDA for use in the diagnosis, mitigation, prevention, treatment, or cure of the H1N1 Flu Virus. The FDA demanded that the distributor immediately cease marketing the product for its remedial purposes or else face seizure of their goods and criminal liability.

TCM products clearly have an audience with U.S. consumers. But, reaching these consumers means compliance with the regulations that serve to protect them. The first step to avoiding an unwanted enforcement action is learning how your product is classified within the regulations and then understanding the regulatory requirements that are imposed by the FDA on the marketing and manufacturing of the product.

To learn more about the classification of a TCM by the FDA and the requirements that will be imposed on a TCM product, please contact any member of the Life Sciences and Medical Products Client Team.

3 Warning Letter to Guilin Hospital of Sino-western Medicine 5/26/09 at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm163617.htm

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